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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANT:	JIA	EXAMINER:	MELLER, M. V.
SERIAL NO.:	10/091,362	ART UNIT:	1654
FILED:	MARCH 1, 2002	CONF. NO.	7281
TITLE:	IDENTIFICATION OF FREE-B-RING FLAVONOIDS AS POTENT COX-2 INHIBITORS		

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Sir:

BRIEF FOR APPELLANT

In furtherance of the Notice of Appeal to the Board of Appeals filed in the above-referenced application on October 29, 2003, Appellants Qi Jia, Timothy C. Nichols, Eric Rhoden and Scott Waite submit this brief in triplicate.

I. REAL PARTY IN INTEREST

The party in interest is UniGen Pharmaceuticals, Inc.

II. RELATED APPEALS AND INTERFERENCES

The undersigned legal representative of Appellant, hereby confirms that there are no known appeals or interferences relating to the present application, or any parent application, which will directly affect or be directly affected by the or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1, 4, 7, 22, 24-27 and 32-34 are pending in the application and stand rejected under a final Office Action mailed August 18, 2003. Claims 2, 3, 5, 6, 8-21, 23 and 28-31 have been canceled. The pending claims are set forth in the Appendix attached hereto. The rejection of all of the pending claims is hereby appealed.

IV. STATUS OF AMENDMENTS

The Amendments filed in this application have all been entered, and the claims in the attached Appendix accurately reflect the current status of the claims.

V. SUMMARY OF THE INVENTION

The present invention relates generally to a method for the prevention and treatment of COX-2 mediated diseases and conditions. The present invention implements a strategy that combines a series of biomolecular screens with a chemical dereplication process to identify active plant extracts and the particular compounds within those extracts that specifically inhibit COX-2 enzymatic activity and inflammation. A total of 1230 plant extracts were screened for their ability to inhibit the peroxidase activity associated with recombinant COX-2. This primary screen identified 22 plant extracts that were further studied for their ability to specifically and selectively inhibit COX-2 *in vitro* in both cell based and whole blood assays. Those extracts that were efficacious *in vitro* were then tested for their ability to inhibit inflammation *in vivo* using a both air pouch and topical ear-swelling models of inflammation when administered by multiple routes (IP and oral). These studies resulted in the discovery of botanical extracts that inhibited COX-2 activity and were efficacious both *in vitro* and *in vivo*. These studies also resulted in the identification of specific free-B-ring flavonoids associated with COX-2 inhibition in each of these extracts. (Specification, page 10, line 24 - page 11, line 7).

As provided in the Specification, (page 4, lines 7-11), the COX-2 enzyme catalyzes two separate reactions: the metabolism of arachidonic acid to form the unstable prostaglandin G2 (PGG2), a cyclooxygenase reaction and the conversion of PGG2 to the endoperoxide PGH2, a peroxidase reaction. The short-lived PGH2 non-enzymatically degrades to PGE2. Prostaglandins, including PGE2, contribute to the pain and fever associated with inflammation.

Inflammation is a complicated biological process involving DNA, mRNA gene expression, different cells, proteins, mediators, enzymes, chemical components, and normal

function of the microcardiovascular system and general immune functions. Using an inflammation animal model, croton oil induced mouse ear swelling, as an example, any agent that possesses any of the following mechanism of actions would yield anti-inflammatory output:

1. Croton oil absorption blocker;
2. Endothelial cells, leukocytes deactivator;
3. Cytokine production down regulator;
4. Histamine blocker;
5. Chemokines blocker;
6. Phospholipids A2 (PLA2) enzyme inhibitor;
7. PLA2 gene expression down regulator;
8. iNOS gene expression down regulator;
9. iNOS inhibitor;
10. Adhesion molecule expression inhibitor;
11. Adhesion molecule ligands;
12. Adhesion molecule receptor binder;
13. Lipoxygenase inhibitor;
14. Lipoxygenase gene down regulator;
15. Peroxidase inhibitor;
16. Free radical scavenging agent;
17. Prostaglandin E2 scavenging agent;
18. Cyclooxygenase gene down regulator; and
19. Cyclooxygenase inhibitor.

Essentially, any drugs, chemicals or natural products that interfere with any of the steps of the inflammation cascade may lead to the reduction in inflammation and can therefore be characterized as anti-inflammatory agents. Cyclooxygenase enzyme inhibitors block only the metabolism of arachidonic acid, which in turn leads to a decrease in the production of the pain-associated mediators prostaglandins. The result of the administration of a COX inhibitor will be a lessening of the pain and vasodilation, as well as, other symptoms related to inflammation.

Claim 1 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. Support for claim 1 can be found in Tables 7 and 8 of the Specification (pages 31 and 32). Claims 4 and 7, which depend from claim 1 are directed to the method of claim 1, wherein said free-B ring flavonoids are isolated from plant parts in general and specific plant parts (page 14, lines 6-8). Claim 22 is directed to the method of claim 1, wherein the composition is administered in a daily dosage of between 2.0 to 200 mg/kg of body weight (Example 9, pages 28-30 and Figures 3 and 4). Claim 32 is drawn to the method of claim 1, wherein the mixture of free-B-ring flavonoids contains at least 50% baicalein and baicalein. Claim 33 is drawn to the method of claim 1 wherein the composition is comprised of 10% to 25% of the mixture of free-B-ring flavonoids.

Support for claims 33 can be found in Example 10 and Table 8 on pages 30-32 of the Specification.

Claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid, wherein said free-B-ring flavonoid is selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. Support for claim 24 can be found in Table 4 on page 25 of the Specification. Claims 25 and 26, which depend from claim 24 are directed to the method of claim 24, wherein said free-B ring flavonoids are isolated from plant parts in general and specific plant parts (page 14, lines 6-8). Claim 27 is directed to the method of claim 24 wherein the composition is administered in a daily dosage of between 2.0 to 200 mg/kg of body weight (Example 9, pages 28-30 and Figures 3 and 4). Claim 34 is drawn to the method of claim 24, wherein the composition is comprised of 10% to 25% of the free-B-ring flavonoid. Support for claim 34 can be found in Example 10 and Table 8 on pages 30-32 of the Specification.

VI. ISSUES

1. Is the rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(a) as being anticipated by Nakajima *et al.* (2001) Planta Med 67:132-135; Krakauer *et al.* (2001) FEBS Letters 500:52-55; Kimura *et al.* (2001) Planta Med 67:331-334; Chi *et al.* (2001) Biochemical Pharmacology 61:1417-1427 or Chen *et al.* (2001) Biochemical Pharmacology 61:1195-1203 proper?

2. Is the rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(b) as being anticipated by Li *et al.* (2000) Immunopharmacology 49:295-306 or Meybeck, U.S. Pat. No. 5,643,598 proper?

3. Is the rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(e) as being anticipated by Xinxian, U.S. Pat. No. 6,290,995; Newmark *et al.*, U.S. Pat. No. 6,264,995; Newmark *et al.*, U.S. Pat. No. 6,391,346; Newmark *et al.*, U.S. Pat. No. 6,387,416 or Kuhrts, U.S. Pat. No. 6,475,530 proper?

4. Is the rejection of claims 1, 4, 7, 22, 24-27 and 32-34 under 35 U.S.C. § 103(a) over Nakajima *et al.* (2001) Planta Med 67:132-135; Krakauer *et al.* (2001) FEBS Letters

500:52-55; Kimura *et al.* (2001) Planta Med 67:331-334; Chi *et al.* (2001) Biochemical Pharmacology 61:1417-1427; Chen *et al.* (2001) Biochemical Pharmacology 61: 1417-1427; Xinxian, U.S. Pat. No. 6,290,995; Newmark *et al.*, U.S. Pat. No. 6,264,995; Newmark *et al.*, U.S. Pat. No. 6,391,346; Newmark *et al.*, U.S. Pat. No. 6,387,416; Kuhrts, U.S. Pat. No. 6,475,530; Li *et al.* (2000) Immunopharmacology 49:295-306 or Meybeck, U.S. Pat. No. 5,643,598 proper?

VII. GROUPING OF THE CLAIMS

For purposes of this appeal, the following groups of claims are considered separately patentable and do not stand or fall together: claims 1, 4, 7, 22, 32 and 33 (Group I), which are drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of a mixture of free-B-ring flavonoids and claims 24, 25, 26, 27 and 34 (Group II), which are drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of a single free-B-ring flavonoid, wherein said free-B-ring flavonoid is selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. In accordance with MPEP § 1206(c)(7), the reasons in support of separate patentability of these two groups of claims are that the claims of Group I are to the genus and the claims of Group II are to individual species within the genus. As discussed in detail below, some of the cited references disclose mixtures of flavonoids and some of the cited references disclose specific flavonoids. In light of this Appellant maintains that these two groups of claims are patentably distinct.

VIII. ARGUMENTS

A. Statement of the Relevant law Pertaining to 35 U.S.C. § 102 Rejections.

The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984); Alco Standard Corp. v. Tennessee Valley Auth., 1 USPQ2d 1337, 1341 (Fed. Cir. 1986). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic v. Genentech Inc., 18 USPQ2d 1001, 1010 (Fed. Cir. 1991, citations omitted). "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention either expressly or inherently." Atlas Powder Co. v. Ireco Inc., 190 F.3d. 1342, 1346 (Fed. Cir. (1999) (quoting In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997)).

1. The rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(a) is improper (Issue 1).

Claims 1, 4, 7 and 24-26 stand rejected under 35 U.S.C. § 102 (a) as being anticipated by Nakajima *et al.* (2001) Planta Med 67:132-135, Krakauer *et al.* (2001) FEBS Letters 500:52-55, Kimura *et al.* (2001) Planta Med 67:331-334, Chi *et al.* (2001) Biochemical Pharmacology 61:1417-1427 or Chen *et al.* (2001) Biochemical Pharmacology 61:1195-1203. The Examiner provides that each of these references "teach administering the claimed extract to a patient/host having a condition where the COX-2 enzyme needs to be inhibited." The Examiner reasons that although Applicant argues that the references do not teach that the COX-2 enzyme needs to be administered, each reference clearly describes that the extract, which inherently has the claimed compound in it, is being administered to treat a COX-2 condition, i.e. cancer, arthritis, asthma, etc.

The Nakajima *et al.* Reference

Nakajima *et al.* ((2001) Planta Med 67:132-135), teach the inhibition of the production of eotaxin by free-B-ring flavonoids isolated from *Scutellaria baicalensis* for the treatment of bronchial asthma. Specifically, four flavonoids isolated from *Scutellaria* root --baicalein, proxylin A, baicalin and skullcapflavon II-- were found to inhibit the production of eotaxin. Eotaxin is a protein produced by dermal fibroblasts in response to interleukin-4 and tumor necrosis factor-α and is related to bronchial diseases, such as allergies and asthma. This protein is not related to cyclooxygenase and has nothing to do with the metabolism of arachidonic acid. The inhibition of the production of eotaxin is completely unrelated to the inhibition of COX-2 activity.

Independent claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprising 10% to 100% of a mixture of free-B-ring flavonoids. The Nakajima *et al.* reference does not disclose or suggest that any of the four compounds or combinations thereof, function as COX-2 inhibitors. Furthermore, there is no evidence to suggest that there would be overlap between indications requiring an inhibitor of eotaxin and those requiring a COX-2 inhibitor. In fact, there is evidence in the literature that COX inhibitors can actually induce an asthma attack. Thus, the use of a COX-2 inhibitor would actually be contraindicated for treatment of asthmatic conditions. Additionally, as noted above, claim 1 is drawn to a composition comprising 10% to 100% of a mixture of free-B-ring

flavonoids. As stated above, the law is clear that to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention either expressly or inherently. When a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim. In the instant case, however, the Nakajima *et al.* reference provides no range for the amount of free-B-ring flavonoids in their composition. Thus, the Nakajima *et al.* reference does not expressly anticipate the claimed range. Furthermore, it cannot be concluded with any degree of certainty that the composition of the Nakajima *et al.* reference must fall within the claimed range. Thus, the Nakajima *et al.* reference does not inherently anticipate the claimed range. As such, Applicant maintains that the Nakajima *et al.* reference does not anticipate independent claim 1. Claims 4, 7 and 22, which depend from claim 1 are also not anticipated by this reference.

Independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a single free-B-ring flavonoid selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. For the reasons discussed above with respect to claim 1, Applicant maintains that the Nakajima *et al.* reference does not anticipate independent claim 24. Additionally, Applicant also maintains that the Nakijima *et al.* reference does not anticipate claims 25 and 26, which depend from claim 24.

The Krakauer *et al.* Reference

Krakauer *et al.* ((2001) FEBS Letters 500:52-55), disclose a method for the treatment of a number of diseases ranging from food poisoning and toxic shock to autoimmune diseases, by treatment with the free-B-ring flavonoid baicalin isolated from *Scutellaria baicalensis*. Krakauer *et al.* postulate that baicalin may be therapeutically useful for mitigating the pathogenic effects of staphylococcal exotoxins by inhibiting the signaling pathways activated by superantigens. There is no evidence that there is any relationship between the inhibition of the signaling pathways activated by superantigens and the inhibition of COX-2 activity.

As noted above, claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. The Krakauer *et al.* reference does not disclose or suggest treatment using a mixture of free-B-ring flavonoids. The Krakauer *et al.* reference also does not disclose or suggest that the free-B-ring flavonoid baicalin or any other free-B-ring flavonoid functions as

COX-2 inhibitor. Furthermore, although there may be some overlap between indications requiring the inhibition of the signaling pathways activated by superantigens and those requiring a COX-2 inhibitor, there is no evidence to suggest that the overlap would be substantial. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of the signaling pathways activated by superantigens would not be effective and visa versa. As stated above, the law is clear that to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention either expressly or inherently. Applicant maintains that the Krakauer *et al.* reference does not anticipate independent claim 1 or dependent claims 4, 7 and 22.

For the reasons discussed above with respect to independent claim 1, Applicant also maintains that the Krakauer *et al.* reference also does not anticipate independent claim 24. Additionally, independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid. As stated above, when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that fall within each of the ranges anticipates the claim. In the instant case, however, the Krakauer *et al.* reference provides no range for the amount of free-B-ring flavonoid in their composition. Thus, the Krakauer *et al.* reference does not expressly anticipate the claimed range. Furthermore, it cannot be concluded with any degree of certainty that the composition of the Krakauer *et al.* reference falls within the claimed range. Thus, the Krakauer *et al.* reference does not inherently anticipate the claimed range. As such, Applicant maintains that the Krakauer *et al.* reference does not anticipate independent claim 24 or dependent claims 25 or 26.

The Kimura *et al.* Reference

Kimura *et al.* ((2001) Planta Med 67:331-334), disclose the inhibition of adhesion molecule expression by the free-B-ring flavonoid baicalein. The baicalein was isolated from the roots of *Scutellaria baicalensis* and dissolved in ethanol to what appears to be a final concentration of less than 0.25% (Kimura *et al.*, page 332, col. 1, lines 1-3). Specifically, the free-B-ring flavonoid baicalein was found to inhibit the expression of both ELAM-1 and ICAM-1. Adhesion molecules are proteins, unrelated to both COX-2 activity and the arachidonic acid pathway. All other free-B-ring flavonoids tested including baicalin and wogonin were determined to have no effect on the inhibition of adhesion molecule expression.

Independent claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprising 10% to 100% of a mixture of free-B-ring flavonoids. The Kimura *et al.* reference does not disclose or suggest a composition of matter comprised of a mixture of free-B-ring flavonoids. In fact, this reference actually teaches away from compositions comprised of mixtures of flavonoids in that only one of the nine compounds tested was actually found to be active. The Kimura *et al.* reference also does not disclose or suggest that any of these compounds function as COX-2 inhibitors. Furthermore, although there may be some overlap between indications requiring inhibition of adhesion molecule expression and those requiring a COX-2 inhibitor, there is no evidence to suggest that the overlap would be one hundred percent. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of adhesion molecule expression would not be effective and visa versa. In fact, baicalin, one of the compounds determined to be inactive with respect to inhibition of adhesion molecule expression is an excellent inhibitor of COX-2 (see Specification, page 25, Table 4). In light of these comments, Applicant maintains that the Nakajima *et al.* reference does not anticipate independent claim 1 or dependent claims 4, 7 and 22.

Independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a single free-B-ring flavonoid. For the reasons discussed above with respect to claim 1, Applicant maintains that the Kimura *et al.* reference also does not anticipate independent claim 24. Additionally, independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid. As stated above, when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim. In the instant case, however, the Kimura *et al.* reference provides that the baicalein was dissolved in ethanol to a final concentration of less than 0.25% (Kimura *et al.*, page 332, col. 1, lines 1-3). This is not within the range of claim 24. Thus, the Kimura *et al.* reference neither expressly nor inherently anticipates the claimed range. As such, Applicant maintains that the Kimura *et al.* reference does not anticipate independent claim 24 or the claims that depend from this claim.

The Chi *et al.* Reference

Chi *et al.* ((2001) Biochemical Pharmacology 61:1195-1203) demonstrate that wogonin, a free-B-ring flavonoid, inhibits nitric oxide (NO) as well as PGE2 production via suppression of the induction/gene expression of both iNOS and COX-2 in LPS-induced RAWcells (page, 1200, col. 1). It was also found that wogonin inhibited PGE2 production more potently than NO production. Gene expression is a measure of mRNA production from DNA. Gene expression down regulation does not necessarily lead to inhibition of the protein itself. Direct COX-2 enzyme inhibition by wogonin was not measured in this study; however, the authors speculated that in addition to the inhibition of the gene expression of COX-2, wogonin also inhibited the activity of the enzyme itself. The authors provided that although the reason for the various sensitivities to inhibition by wogonin was not known, "[i]t may be explained in part by the fact that, in addition to the suppressive effects of wogonin on iNOS and COX-2 induction, it also inhibited COX-2 activity from the homogenate of LPS-induced RAW 264.7 cells" (page 1200; col. 1). It is clear that Chi *et al.* are merely speculating that wogonin directly inhibits the COX-2 enzyme. There was no direct measurement of COX-2 enzyme inhibition activity of wogonin in Chi's report and it was expressly stated that the reason for the various sensitivities was not known.

As noted above, claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. The Chi *et al.* reference does not disclose or suggest a composition of matter comprised of a mixture of free-B-ring flavonoids, but rather discloses the purported effect of one free-B-ring flavonoid, wogonin on COX-2 inhibition. With reference to the Specification, it can be seen that relative to the other free-B-ring flavonoids tested, such as baicalein (100% inhibition) and baicalin (97% inhibition), wogonin is actually a relatively poor COX-2 inhibitor (12% inhibition). (Specification, page 25, Table 4). As discussed in detail above, since claim 1 is drawn to a composition comprised of a mixture of free-B-ring flavonoids neither this claim nor the claims that depend from this claim are anticipated by the Chi *et al.* reference.

Independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a single free-B-ring flavonoid, wherein said free-B-ring flavonoid is selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. Claim 24 does not include the free-B-ring flavonoid wogonin and is therefore not anticipated by the Chi *et al.* reference. For

the same reason the claims that depend from independent claim 24 are also not anticipated by the Chi *et al.* reference.

The Chen *et al.* Reference

Chen *et al.* ((2001) Biochemical Pharmacology 61:1417-1427) examined three free-B-ring flavonoids: wogonin, baicalin and baicalein for their effects on LPS-induced NO production and iNOS and COX-2 gene expression. As noted above, gene expression is a measure of mRNA production from DNA and further, gene expression down regulation does not necessarily lead to inhibition of the protein itself. In this study, Chen *et al.* also indirectly examined the effects of baicalin, baicalein and wogonin on iNOS and COX-2 enzyme activity, using a cell model of LPS stimulated prostaglandin E2 (PGE2) production, as described in Section 3.3 beginning on page 1420 of the reference. The authors conclude that "[w]ogonin, but not baicalin or baicalein, inhibited LPS-induced COX-2 expression." (Page 1426, col. 1). The authors also expressly provide that "[t]hese compounds [wogonin, baicalin and baicalein] did not affect iNOS and COX-2 (enzyme) activity." (Page 1426, col. 1). Thus, Chen *et al.* found no direct enzyme inhibition by any of the three free-B-ring flavonoids evaluated.

As noted above, claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. The Chen *et al.* reference does not disclose or suggest a composition of matter comprised of a mixture of free-B-ring flavonoids. In fact, this reference clearly teaches away from the use of compositions comprised of mixtures of flavonoids for the inhibition of COX-2 in that Chen *et al.* actually reports that no direct enzyme inhibition by any of the free-B-ring flavonoids was found. As discussed in detail above, since claim 1 and its dependent claims are drawn to a composition comprised of a mixture of free-B-ring flavonoids these claims are not anticipated by the Chen *et al.* reference.

Independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a single free-B-ring flavonoid, wherein said free-B-ring flavonoid is selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. As noted above, claim 24 does not include the free-B-ring flavonoid wogonin and the Chen *et al.* reference expressly provides that baicalein and baicalin do not inhibit the COX-2 enzyme. Claim 24 and its dependent claims are therefore not anticipated by the Chen *et al.* reference.

2. The rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(b) is improper (Issue 2).

Claims 1, 4, 7 and 24-26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Li *et al.* (2000) Immunopharmacology 49:295-306 or Meybeck U.S. Pat. No. 5,643,598. The Examiner provides that each of these references "teach administering the claimed extract to a patient/host having a condition where the COX-2 enzyme needs to be inhibited." The Examiner reasons that although Applicant argues that the references do not teach that the COX-2 enzyme needs to be administered, each reference clearly describes that the extract, which inherently has the claimed compound in it, is being administered to treat a COX-2 condition, i.e. cancer, arthritis, asthma, etc.

The Li *et al.* Reference

Li *et al.* ((2000) Immunopharmacology 49:295-306) teach the inhibition of the binding of a number of chemokines to human leukocytes via selective binding to chemokine ligands by the free-B-ring flavonoid baicalin, isolated from *Scutellaria baicalensis*. Chemokines are chemotactic molecules that attract immune cells, helping them to "home" to sites of inflammation. Frequently, the cells producing these regulatory molecules also bear receptors for them, participating in a complex network of self-regulating and local interactions that orchestrate the proliferation of immune cells and the subsequent decline of immune activity. COX mediated inflammation pathways are downstream biological responses. Inhibition of the binding of chemokines is unrelated to the arachidonic acid metabolism by COX-2.

As noted above, claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. The Li *et al.* reference does not disclose or suggest using a mixture of free-B-ring flavonoids. The Li *et al.* reference also does not disclose or suggest that the free-B-ring flavonoid baicalin or any other free-B-ring flavonoid functions as a COX-2 inhibitor. Furthermore, although there may be some overlap between indications requiring an inhibitor of the binding of chemokines to human leukocytes by the free-B-ring flavonoid baicalin and those requiring a COX-2 inhibitor, there is no evidence to suggest that the overlap would be substantial. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of the binding of chemokines to human leukocytes would not be effective and visa versa. As stated above, the law is clear that to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention

either expressly or inherently. Applicant maintains that the Li *et al.* reference does not satisfy this criterion and therefore does not anticipate independent claim 1 or the claims that depend from this claim.

For the reasons discussed above with respect to independent claim 1, Applicant maintains that the Li *et al.* reference also does not anticipate independent claim 24.

The Meybeck Reference

Meybeck (U.S. Pat. No. 5,643,598) teaches a method of formulating *Scutellaria* extracts or at least one active substance isolated from such extracts in liposomes for topical usage having anti-allergic, anti-inflammatory and anti-aging activity. A number of free-B-ring flavonoids, including wogonin, baicalein, scullcapflavone II and baicalin are characterized as antibacterial compounds, as described in the section entitled "Extraction and Isolation of the Antibacterial Components" (Specification, col. 6) and illustrated in Figure 2. With reference to Table II (Specification, col. 11-12), the *Scutellaria* extract in gel exhibited no anti-inflammatory effect (1.1%) when not incorporated into a liposome as illustrated in Figure 1, Table II (Specification, col. 11) and as provided in the Specification (col. 12, lines 8-11). Only the liposome formulated extract had a significant anti-inflammatory effect (69.6%). A moderate effect (30.7%) was observed from the empty liposome. Thus, the Meybeck reference actually teaches away from the method of this invention with respect to the anti-inflammatory activity of these compositions. Additionally, Meybeck neither teaches nor suggests the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors, therefore Meybeck does not anticipate the claims of this invention, which are drawn to the inhibition of the COX-2 enzyme. Finally, the amount of free-B-ring flavonoid or mixtures thereof in the formulation taught by Meybeck is significantly less than the amount set forth in the claims. Meybeck claims a *Scutellaria* extract (alcoholic, aqueous or hydroalcoholic) formulated in a ratio of between 0.00001 to 2% by weight of the extract or any active substance contained in the extract, in an anti-inflammatory composition for topical applications. (Col. 6, lines 45-50). The claims of this invention are drawn to a composition comprising 10% to 100% (claims 1 and 24) of the free-B-ring flavonoid or mixtures thereof.

As stated above, anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. For all of the reasons discussed above, Applicant maintains that the Meybeck reference does not satisfy this criterion and therefore does not anticipate independent claims 1 or 24 of the instant invention.

3. The rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(e) is improper (Issue 3).

Claims 1, 4, 7 and 24-26 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Xinxian, U.S. Pat. No. 6,290,995; Newmark *et al.*, U.S. Pat. No. 6,264,995; Newmark *et al.*, U.S. Pat. No. 6,391,346; Newmark *et al.*, U.S. Pat. No. 6,387,416 or Kuhrts, U.S. Pat. No. 6,475,530. The Examiner provides that each of these references "teach administering the claimed extract to a patient/host having a condition where the COX-2 enzyme needs to be inhibited." The Examiner provides that although Applicants argue that the extract is being used for a different purpose other than in a method for inhibiting COX-2, the fact of the matter is that each reference clearly describes that the extract is being administered to treat a COX-2 condition, i.e. cancer, arthritis, asthma, etc.

The Xinxian Reference

Xinxian (U.S. Pat. No. 6,290,995) teaches a method for producing a pharmaceutical composition of baicalin in combination with the alkaloid berberine for use in the treatment of cancer and control of cancer cells. Example 5 demonstrates that baicalin inhibits DNA synthesis of TPA-stimulated mouse epidermis and therefore prevents epidermis cancer (col. 6, lines 22-25). Example 6 demonstrates the effectiveness of baicalin in the treatment of gastric cancer. In this example, the mixture of baicalin and berberine is shown to inhibit levels of DNA methylation, p^{53} mutations, ^{17}p allelic loss of cancer cells and increase the function of tumor suppressor of gastric cancer cells. Example 7 demonstrates that baicalin inhibits oncogenes and Example 8 demonstrates that baicalin inhibits tumor cell proliferation and prevents tumor incidence in an animal model *in vivo*. The Xinxian patent does not teach or suggest that the free-B-ring flavonoid, baicalin, isolated from *Scutellaria baicalensis* inhibits COX-2 activity. Nor does the Xinxian patent disclose or suggest an active composition of matter comprised of a mixture of free-B-ring flavonoids. Finally, although there may be some overlap between indications requiring an inhibitor of DNA synthesis etc. and those requiring a COX-2 inhibitor, there is no evidence to suggest that the overlap would be substantial. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of DNA synthesis would not be effective and visa versa. As stated above, the law is clear that to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention either expressly or inherently. For all of the reasons discussed above with respect to

the other references cited by the Examiner, Applicant maintains that the Xinxian reference does not anticipate independent claims 1 or 24 of the instant invention.

The Newmark References

Newmark *et al.* (U.S. Pat. No. 6,264,995, the '995 patent), teach an herbal composition, which contains extracts from 13 different plants, including *Scutellaria baicalensis*. The patent provides that the extract reduces inflammation in bones and joints by inhibiting the COX-2 enzyme. The only definition of the *Scutellaria baicalensis* root extract is 5:1, which generally refers to 5 parts of plant root yielding one part of the extract. Considering that more than 58 compounds have been isolated from *Scutellaria baicalensis*, a hydroalcoholic extract could contain any number of compounds including, but not limited to alkaloids, benzyl alcohol glycosides, lignans, benzopyranones, amino acids, phytosterols, monosugars, flavones and flavanones. The '995 patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. The present invention, on the other hand, discloses and claims a specific class of compounds, free-B-ring flavonoids, as having COX-2 inhibitory activity. Thus, even though the Newmark *et al.* composition likely contains free-B-ring flavonoids, there is no disclosure or suggestion that these compounds are COX-2 inhibitors.

Applicant maintains that there are many advantages to isolating and identifying specific biologically active compounds from a composition of matter that could contain literally thousands of compounds. Once identified, a class of compounds can be purified and concentrated to provide a more effective biological agent. Additionally, the compounds can be chemically modified to provide a composition of matter that is more active and/or less toxic. Finally, once isolated and identified a specific compound or class of compounds can be studied to determine the exact biological activity and mode of action, thus enabling more specific targeting of the compound or class of compounds for the treatment of particular diseases or conditions.

Additionally, with reference to the Table provided in the Newmark patent (col. 12), the extract of *Scutellaria baicalensis* accounted for approximately 2.6% by weight of the formulation. As discussed in detail below, the amount of free-B-ring flavonoid or mixtures thereof in the formulation taught by Newmark *et al.* is significantly less than the amount set forth in the claims of the instant invention. In the case of chemical compounds slight changes, including a mere change in the amount of a compound, have been found to be sufficient to

change an old compound into a new one. (Schering Corp. v. Precision-Cosmet Co. 614 F. Supp. 1368, 1374 (D. Del. 1985)). The law is clear that new uses of known processes may be patentable. Therefore, Applicant maintains that Newmark *et al.* does not anticipate independent claims 1 and 24.

In the roots of *Scutellaria baicalensis*, the baicalin content (which accounts for approximately 80% of the total free-B-ring flavonoid content) is approximately 10% of the weight of the roots. If an average of 10% is used as a benchmark, one can obtain 10 grams of baicalin from 100 grams of dry root, assuming the extraction efficiency is 100%. With reference to the Table provided in the Newmark patent (col. 12), the *Scutellaria Baicalensis* root extract used in the formulation is a 5:1 extract, which means from 5 parts (grams/kilograms) of root, 1 part (grams/kilograms) of extract by weight is obtained. The Table further provides that the quantity of the extract used in the formulation is 20 mg. Thus, 100 mg of dry root was required to provide this amount of extract (20 mg x 5 = 100 mg dry root). Assuming for the sake of argument, that the maximum amount of baicalin/free-B-ring flavonoids was extracted, the baicalin content in the 20 mg of root extract would be approximately 10 mg. (100 mg root extract x 10% = 10 mg baicalin in the 20 mg of root extract). Thus, the maximum purity of baicalin in the 20 mg of extract is 50%. Thus, based on the information provided in the Table, the maximum % of baicalin in Newmark's formulation is 1.3% (10 mg/770 mg total dry weight). Finally, if 20 mg of a 5:1 extract (10 mg baicalin) is administered to an average weight adult at 75 kg (165 lb) body weight, the dosage range for the extract is 0.27 mg/kg (0.14 mg/kg for baicalin). The claims of this invention are drawn to administering a free-B-ring flavonoid or mixture thereof wherein the content of said flavonoid or mixture thereof is 10% to 100% (claims 1 and 24) and the dosage range is 2.0 to 200 mg/kg of body weight. Therefore, the Newmark *et al.* patent does not anticipate the claims.

Newmark *et al.* (U.S. Pat. No. 6,387,416), describe an orally or topically administered composition capable of reducing inflammation. With reference to the Table (Specification col. 8-9), the maximum % of baicalin in the formulation described in this patent is approximately the same as the '995 patent discussed above (20 mg of a 5:1 extract/760 mg total). Additionally, as discussed above Newmark *et al.* neither teach nor suggest the use of free-B-ring flavonoids as COX-2 inhibitors. Therefore, based on the reasoning above, this patent does not anticipate the claims of this invention, as amended.

Newmark *et al.* (U.S. Pat. No. 6,391,346), describe an orally administered composition capable of reducing inflammation in animals. The composition contains 13 extracts, including an extract from the plant *Scutellaria baicalensis*. The only definition of the *Scutellaria baicalensis* root extract provided in the Specification is that it is 5:1, which as noted above, generally refers to 5 parts of plant roots yielding one part of the extract. Also as noted above, considering that more than 58 compounds have been isolated from *Scutellaria baicalensis*, a hydroalcoholic extract could contain any number of compounds including, but not limited to alkaloids, benzyl alcohol glycosides, lignans, benzopyranones, amino acids, phytosterols, monosugars, flavones and flavanones. Additionally, the patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. The extract from *Scutellaria baicalensis* accounted for approximately 12% to 18% by weight of total weight of the formulation. This amounts to a maximum of 6% to 9% by weight of free-B-ring flavonoids in the formulation. As discussed above, the claims of the instant invention provide that the free-B-ring flavonoid or mixture thereof is present in an amount greater than 10%. Therefore, based on the above reasoning, this patent does not anticipate the claims of this invention.

The Kuhrts Reference

Kuhrts (U.S. Pat. No. 6,475,530) describe weight loss compositions that combine a weight loss effective compound and a botanical COX-2 inhibitor. The plant "*Scutellaria baicalensis*" was referred to in the patent as a COX-2 inhibitor. There is no further description, however, of the material or extract of *Scutellaria baicalensis* being used. Nor is there any reference to amounts or dosage. "*Scutellaria baicalensis*" is the Latin name of a specific species of plant. It is commonly known that different parts of a plant contain totally different types of compounds in different concentrations. To date, there have been more than 58 compounds isolated from various parts of *Scutellaria baicalensis.* These compounds include alkaloids, benzyl alcohol glycosides, lignans, benzopyranones, amino acids, phytosterols, monosugars, flavones, and flavanones. The Kuhrts patent provides no examples to substantiate the claim of a COX inhibitor from *Scutellaria baicalensis*. Nor does the Kuhrts patent teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. Therefore, for the reasons discussed above, Applicant maintains that the Kuhrts patent does not anticipate the claims of the instant invention.

B. Statement of the Relevant law Pertaining to 35 U.S.C. § 103 Rejections.

The Examiner bears the burden of establishing a prima facie case of obviousness. In determining obviousness, one must focus on Applicant's invention as a whole. Symbol Technologies Inc. v. Opticon Inc., 19 USPQ2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is:

> whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success. . . . Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure.

In re Dow Chemical, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

Where the prior art teaches generically, and no indication is given as to which of the parameters or choices is desirable or likely to be successful, then the fact that the claimed invention is within the generic teachings of the prior art does not render the claimed invention obvious. Under such circumstances, i.e., where the artisan is invited to simply try each of numerous possible choices, *prima facie* obviousness is not established. Instead, it is said that the invitation to investigate various possibilities of a genus can, at most, only render the claimed invention "obvious to try," which is not the proper standard under Section 103. In re O'Farrell, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988).

4. The rejection of claims 1, 4, 7, 22, 24-27 and 32-34 under 35 U.S.C. § 103(a) is improper (Issue 4).

Claims 1, 4, 7, 22, 24-27 and 32-34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nakajima *et al.* (2001) Planta Med 67:132-135; Krakauer *et al.* (2001) FEBS Letters 500:52-55; Kimura *et al.* (2001) Planta Med 67:331-334; Chi *et al.* (2001) Biochemical Pharmacology 61:1417-1427; Chen *et al.* (2001) Biochemical Pharmacology 61: 1417-1427; Xinxian, U.S. Pat. No. 6,290,995; Newmark *et al.*, U.S. Pat. No. 6,264,995; Newmark *et al.*, U.S. Pat. No. 6,391,346; Newmark *et al.*, U.S. Pat. No. 6,387,416; Kuhrts, U.S. Pat. No. 6,475,530; Li *et al.* (2000) Immunopharmacology 49:295-306 or Meybeck, U.S. Pat. No. 5,643,598. The Examiner provides that each of these references "teach administering the claimed extract to a patient/host having a condition where the COX-2 enzyme needs to be inhibited." The Examiner provides that although Applicants argue that the extract is being used for a different purpose other than in a method for inhibiting COX-2, the fact of the matter is that each reference clearly

describes that the extract is being administered to treat a COX-2 condition, i.e. cancer, arthritis, asthma, etc.

Appellant asserts that the cited references either alone or in combination, do not disclose or suggest the present invention, and therefore, do not render the present invention obvious. As noted above, the present invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprising 10% to 100% of a free-B-ring flavonoid (claim 24) or mixtures thereof (claim 1). The present invention implements a strategy that combines a series of biomolecular screens with a chemical dereplication process to identify active plant extracts and the particular compounds within those extracts that specifically inhibit COX-2 enzymatic activity and inflammation. A total of 1230 plant extracts were screened for their ability to inhibit the peroxidase activity associated with recombinant COX-2. This primary screen identified 22 plant extracts that were further studied for their ability to specifically and selectively inhibit COX-2 *in vitro* in both cell based and whole blood assays. Those extracts that were efficacious *in vitro* were then tested for their ability to inhibit inflammation *in vivo* using a both air pouch and topical ear-swelling models of inflammation when administered by multiple routes (IP and oral). These studies resulted in the discovery of botanical extracts that inhibited COX-2 activity and were efficacious both *in vitro* and *in vivo*. These studies also resulted in the identification of specific free-B-ring flavonoids associated with COX-2 inhibition in each of these extracts. (Specification, page 10, line 24- page 11, line 7). As discussed in detail below, Appellant asserts that the discovery of this class of COX-2 inhibitors was not motivated by the prior art relied upon by the Examiner and further that this class of COX-2 inhibitors is not rendered obvious by the art relied upon by the Examiner.

Nakajima *et al.* ((2001) Planta Med 67:132-135), teach the inhibition of the production of eotaxin by free-B-ring flavonoids isolated from *Scutellaria baicalensis* for the treatment of bronchial asthma. Specifically, four flavonoids isolated from *Scutellaria* root --baicalein, proxylin A, baicalin and skullcapflavon II-- were found to inhibit the production of eotaxin. As provided above, this protein is not related to cyclooxygenase and has nothing to do with the metabolism of arachidonic acid. The Nakajima *et al.* reference does not disclose or suggest that any of the four compounds or combinations thereof, function as COX-2 inhibitors. Furthermore, there is no evidence to suggest that there would be overlap between indications requiring an inhibitor of eotaxin and those requiring a COX-2 inhibitor. Applicant asserts therefore that one would not be motivated by this reference to use a free-B-ring flavonoid or mixtures thereof as a

COX-2 inhibitor. As stated above, both the suggestion and the expectation of success must be found in the cited reference.

Krakauer *et al.* ((2001) FEBS Letters 500:52-55), disclose a method for the treatment of a number of diseases ranging from food poisoning and toxic shock to autoimmune diseases by treatment with the free-B-ring flavonoid baicalin isolated from *Scutellaria baicalensis*. Krakauer *et al.* postulate that baicalin may be therapeutically useful for mitigating the pathogenic effects of staphylococcal exotoxins by inhibiting the signaling pathways activated by superantigens. There is no evidence that there is any relationship between the inhibition of the signaling pathways activated by superantigens and the inhibition of COX-2 activity. For the reasons stated above, Applicant asserts therefore that one would not be motivated by this reference to use a free-B-ring flavonoid or mixtures thereof as potential COX-2 inhibitors.

Kimura *et al.* ((2001) Planta Med 67:331-334), disclose the inhibition of adhesion molecule expression by the free-B-ring flavonoid baicalein. The baicalein was isolated from the roots of *Scutellaria baicalensis* and dissolved in ethanol to what appears to be a final concentration of less than 0.25% (Kimura *et al.*, page 332, col. 1, lines 1-3). Specifically, the free-B-ring flavonoid baicalein was found to inhibit the expression of both ELAM-1 and ICAM-1. All other free-B-ring flavonoids tested including baicalin and wogonin were determined to have no effect on the inhibition of adhesion molecule expression. Independent claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprising 10% to 100% of a mixture of free-B-ring flavonoids. The Kimura *et al.* reference does not disclose or suggest a composition of matter comprised of a mixture of free-B-ring flavonoids. In fact, as provided above, this reference actually teaches away from compositions comprised of mixtures of flavonoids in that only one of the nine compounds tested was actually found to be active. The Kimura *et al.* reference also does not disclose or suggest that any of these compounds function as COX-2 inhibitors. In fact, baicalin, one of the compounds determined to be inactive with respect to inhibition of adhesion molecule expression is an excellent inhibitor of COX-2 (see Specification, page 25, Table 4).

Additionally, the claims of the instant invention are drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid. The Kimura *et al.* reference provides that the baicalein was dissolved in ethanol to a final concentration of less than 0.25% (Kimura *et al.*, page 332, col. 1, lines 1-3). This is not within the range of any of the claims of this invention. The Examiner provides, however, that

the amounts used are simply the choice of the artisan to use in an effort to optimize the desired results. In response to this, however, if one does not even know that the compounds of interest are COX-2 inhibitors, one would not be motivated to optimize an unknown result by altering concentration. For the reasons discussed above, Applicant asserts therefore that one would not be motivated by this reference to use a free-B-ring flavonoid or mixtures thereof as potential COX-2 inhibitors.

Chi *et al.* ((2001) Biochemical Pharmacology 61:1195-1203) demonstrate that wogonin, a free-B-ring flavonoid, inhibits nitric oxide (NO) as well as PGE2 production via suppression of the induction/gene expression of both iNOS and COX-2 in LPS-induced RAWcells (page, 1200, col. 1). The authors provided that although the reason for the various sensitivities to inhibition by wogonin was not known, "[i]t may be explained in part by the fact that, in addition to the suppressive effects of wogonin on iNOS and COX-2 induction, it also inhibited COX-2 activity from the homogenate of LPS-induced RAW 264.7 cells" (page 1200; col. 1). As noted above, claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. The Chi *et al.* reference does not disclose or suggest a composition of matter comprised of a mixture of free-B-ring flavonoids, but rather discloses the purported effect of one free-B-ring flavonoid, wogonin on COX-2 inhibition. With reference to the Specification, it can be seen that relative to the other free-B-ring flavonoids tested, such as baicalein (100% inhibition) and baicalin (97% inhibition), wogonin is actually a relatively poor COX-2 inhibitor (12% inhibition). (Specification, page 25, Table 4).

Independent claim 24 is drawn to drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid, wherein said free-B-ring flavonoid is selected from the group consisting of, baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. As amended, claim 24 excludes the free-B-ring flavonoid wogonin.

Chen *et al.* ((2001) Biochemical Pharmacology 61:1417-1427) examined three free-B-ring flavonoids: wogonin, baicalin and baicalein for their effects on LPS-induced NO production and iNOS and COX-2 gene expression. In this study, Chen *et al.* also indirectly examined the effects of baicalin, baicalein and wogonin on iNOS and COX-2 enzyme activity, using a cell model of LPS stimulated prostaglandin E2 (PGE2) production. The authors conclude that "[w]ogonin, but not baicalin or baicalein, inhibited LPS-induced COX-2 expression." (Page

1426, col. 1). The authors also expressly provide that "[t]hese compounds [wogonin, baicalin and baicalein] did not affect iNOS and COX-2 (enzyme) activity." (Page 1426, col. 1). Thus, Chen *et al.* found no direct enzyme inhibition by any of the three free-B-ring flavonoids evaluated.

As noted above, the present invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid or mixtures thereof. The Chen *et al.* reference actually teaches away from the method of this invention in that Chen *et al.* report that no direct enzyme inhibition by any of the free-B-ring flavonoids was found. Furthermore, when combined with the Chi reference, Applicant maintains that there would be little motivation to use a free-B-ring flavonoid or mixtures thereof as potential COX-2 inhibitors. While the Chi *et al.* reference merely speculates that wogonin inhibits the COX-2 enzyme, the Chen *et al.* reference expressly provides that there was no direct COX-2 inhibition by any of the free-B-ring flavonoids tested.

Li *et al.* ((2000) Immunopharmacology 49:295-306) teach the inhibition of the binding of a number of chemokines to human leukocytes via selective binding to chemokine ligands by the free-B-ring flavonoid baicalin, isolated from *Scutellaria baicalensis*. As noted above, inhibition of the binding of chemokines is unrelated to the arachidonic acid metabolism by COX-2. The Li *et al.* reference does not disclose or suggest using a mixture of free-B-ring flavonoids. The Li *et al.* reference also does not disclose or suggest that the free-B-ring flavonoid baicalin or any other free-B-ring flavonoid functions as a COX-2 inhibitor. Furthermore, although there may be some overlap between indications requiring an inhibitor of the binding of chemokines to human leukocytes by the free-B-ring flavonoid baicalin and those requiring a COX-2 inhibitor, there is no evidence to suggest that the overlap would be substantial. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of the binding of chemokines to human leukocytes would not be effective and visa versa. For the reasons discussed above, Applicant asserts therefore that one would not be motivated by this reference to use a free-B-ring flavonoid or mixtures thereof as potential COX-2 inhibitors.

Meybeck (U.S. Pat. No. 5,643,598) teaches a method of formulating *Scutellaria* extracts or at least one active substance isolated from such extracts in liposomes for topical usage having anti-allergic, anti-inflammatory and anti-aging activity. A number of free-B-ring flavonoids, including wogonin, baicalein, scullcapflavone II and baicalin are characterized as antibacterial

compounds. With reference to Table II of the Maybeck reference (Specification, col. 11-12), the *Scutellaria* extract in gel exhibited **no** anti-inflammatory effect (1.1%) when not incorporated into a liposome as illustrated in Figure 1, Table II (Specification, col. 11) and as provided in the Specification (col. 12, lines 8-11). Thus, the Meybeck reference actually teaches away from the method of this invention with respect to the anti-inflammatory activity of these compositions. Additionally, Meybeck neither teaches nor suggests the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. Finally, the amount of free-B-ring flavonoid or mixtures thereof in the formulation taught by Meybeck is significantly less than the amount set forth in the claims of the instant invention. Meybeck claims a *Scutellaria* extract (alcoholic, aqueous or hydroalcoholic) formulated in a ratio of between 0.00001 to 2% by weight of the extract or any active substance contained in the extract, in an anti-inflammatory composition for topical applications. (Col. 6, lines 45-50). The claims of this invention are drawn to a composition comprising 10% to 100% (claims 1 and 24) or 10% to 25% (claims 33 and 34) of the free-B-ring flavonoid or mixtures thereof. As provided above, although the Examiner provides that the amounts used are simply the choice of the artisan in an effort to optimize the desired results, if one does not even know that the compounds of interest are COX-2 inhibitors, one would not be motivated to optimize an unknown result by altering concentrations.

Xinxian (U.S. Pat. No. 6,290,995) teaches a method for producing a pharmaceutical composition of baicalin for use in the treatment of cancer and control of cancer cells. Baicalin is shown to inhibit DNA synthesis, to inhibit levels of DNA methylation, p^{53} mutations, ^{17}p allelic loss of cancer cells and to inhibit oncogenes. The Xinxian patent does not teach or suggest that the free-B-ring flavonoid baicalin inhibits COX-2 activity. Nor does the Xinxian patent disclose or suggest an active composition of matter comprised of a mixture of free-B-ring flavonoids. Finally, although there may be some overlap between indications requiring an inhibitor of DNA synthesis etc. and those requiring a COX-2 inhibitor, there is no evidence to suggest that this overlap would be substantial. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of DNA synthesis would not be effective and visa versa. For all of the reasons discussed above with respect to the other references cited by the Examiner, Applicant maintains that the Xinxian reference does not render the present invention obvious.

Newmark *et al.* (U.S. Pat. No. 6,264,995, the '995 patent), teach an herbal composition, which contains extracts from 13 different plants, including *Scutellaria baicalensis*. The patent

provides that the extract reduces inflammation in bones and joints by inhibiting the COX-2 enzyme. The only definition of the *Scutellaria baicalensis* root extract is 5:1, which generally refers to 5 parts of plant root yielding one part of the extract. Considering that more than 58 compounds have been isolated from *Scutellaria baicalensis*, a hydroalcoholic extract could contain any number of compounds. The '995 patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. The present invention, on the other hand, discloses and claims a specific class of compounds, free-B-ring flavonoids, as having COX-2 inhibitory activity. Thus, even though the Newmark *et al.* composition likely contains free-B-ring flavonoids, there is no disclosure or suggestion that these compounds are COX-2 inhibitors.

Applicant maintains that there are many advantages to isolating and identifying specific biologically active compounds from a composition of matter that could contain literally thousands of compounds. Once identified a class of compounds can be purified and concentrated to provide a more effective biological agent. Additionally, the compounds can be chemically modified to provide a composition of matter that is more active and/or less toxic. Finally, once isolated and identified a specific compound or class of compounds can be studied to determine the exact biological activity and mode of action, thus enabling more specific targeting of the compound or class of compounds to treatment of particular diseases or conditions. Contrary to the Examiner's assertion that optimization of factors such as concentration is standard practice, unless one knows what specific compound or class of compounds is exhibiting the desired activity, one cannot possibly optimize the concentration of that compound or class of compounds.

Newmark *et al.* (U.S. Pat. No. 6,387,416), describe an orally or topically administered composition capable of reducing inflammation. With reference to the Table (Specification col. 8-9), the maximum % of baicalin in the formulation described in this patent is approximately the same as the '995 patent discussed above. (20 mg of a 5:1 extract/760 mg total). Additionally, as discussed above Newmark *et al.* neither teach nor suggest the use of free-B-ring flavonoids as COX-2 inhibitors. Newmark *et al.* (U.S. Pat. No. 6,391,346), describe an orally administered composition capable of reducing inflammation in animals. The composition contains 13 extracts, including an extract from the plant *Scutellaria baicalensis*. The only definition of the *Scutellaria baicalensis* root extract provided in the Specification is that it is 5:1, which as noted above, generally refers to 5 parts of plant roots yielding one part of the extract. Also as noted

above, considering that more than 58 compounds have been isolated from *Scutellaria baicalensis*, a hydroalcoholic extract could contain any number of compounds. Additionally, the patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. Therefore, based on the above reasoning, Applicant asserts that none of the cited Newmark *et al.* patents renders the method of the present invention obvious.

Kuhrts (U.S. Pat. No. 6,475,530) describe weight loss compositions that combine a weight loss effective compound and a botanical COX-2 inhibitor. The plant *Scutellaria baicalensis* was referred to in the patent as a COX-2 inhibitor. There is no further description, however, of the material or extract of *Scutellaria baicalensis* being used. Nor is there any reference to amounts or dosage. "*Scutellaria baicalensis*" is the Latin name of a specific species of plant. As a commonly known that different parts of a plant contain totally different types of compounds in different concentrations. To date, there have been more than 58 compounds isolated from various parts of *Scutellaria baicalensis.* The Kuhrts patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. Therefore, for the reasons discussed above, Applicant maintains that the Kuhrts patent does not render the present method obvious.

For the foregoing reasons, Appellant maintains that none of the references cited by the Examiner, either alone or in combination render the present invention obvious and therefore the claims are patentable.

IX. CONCLUSION

In view of the foregoing arguments, Appellant submits that none of the references cited by the Examiner, either alone or in combination anticipate the claims of the instant invention or render the present invention obvious. It is therefore, respectfully requested that the claims be allowed to issue.

Enclosed is a check in the amount of $ 330.00 for the filing of this Appeal Brief. It is believed that no other fees are due with this Appeal Brief. If this is in error, this constitutes a request for any needed extension of time and an authorization to charge all fees therefore to Deposit Account No. 19-5117 if not otherwise specifically requested. In addition, the undersigned authorizes the charge of any additional fees associated with the filing of this document to Deposit Account No. 19-5117.

Respectfully submitted,

Date: December 29, 2003

Rosemary P. Kellogg, #39,726
Swanson & Bratschun, LLC
1745 Shea Center Drive, Suite 330
Highlands Ranch, CO 80129
(303) 268-0066 Telephone
(303) 268-0065 Facsimile

cc: Qi Jia

APPENDIX TO APPELLANT'S BRIEF

The following claims 1, 4, 7, 22, 24-27 and 32-34 are pending in the instant application.

1. A method for inhibiting the cyclooxygenase enzyme COX-2 comprising administering to a host in need thereof a composition comprising 10% to 100% of a mixture of Free-B-Ring flavonoids; wherein said composition is isolated from a plant selected from the Labiatae family, the Scutellaria genus and the *Scutellaria baicalensis* species.

4. The method of claim 1 wherein said Free-B-Ring flavonoids are isolated from a plant part.

7. The method of claim 4 wherein the Free-B-Ring flavonoid is isolated from a plant part selected from the group consisting of stems, stem barks, twigs, tubers, roots, root barks, young shoots, seeds, rhizomes, flowers and other reproductive organs, leaves and other aerial parts.

22. The method of claim 1 wherein the composition of Free-B-Ring flavonoids is administered in a daily dosage selected from 2.0 to 200 mg/kg of body weight.

24. A method for inhibiting the cyclooxygenase enzyme COX-2 comprising administering to a host in need thereof a composition comprised of 10% to 100% of a Free-B-Ring flavonoid; wherein said Free-B-Ring flavonoid is selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin, wherein said composition is isolated from a plant selected from the Labiatae family, the Scutellaria genus and the *Scutellaria baicalensis* species.

25. The method of claim 24 wherein said Free-B-Ring flavonoid is isolated from a plant part.

26. The method of claim 25 wherein the plant part is selected from the group consisting of stems, stem barks, twigs, tubers, roots, root barks, young shoots, seeds, rhizomes, flowers and other reproductive organs, leaves and other aerial parts.

27. The method of claim 24 wherein the composition of Free-B-Ring flavonoid is administered in a daily dosage selected from 2.0 to 200 mg/kg of body weight.

32. The method of claim 1 wherein said mixture of Free-B-Ring flavonoids contain at least 50% baicalin and baicalein.

33. The method of claim 1 wherein said composition is comprised of 10% to 25% of a mixture of Free-B-Ring flavonoids.

34. The method of claim 24 wherein said composition is comprised of 10% to 25% of a Free-B-Ring flavonoid.

LEXSEE

LINDEMANN MASCHINENFABRIK GMBH, Appellant, v. AMERICAN HOIST AND DERRICK COMPANY, HARRIS PRESS AND SHEAR DIVISION, COMMERCIAL METALS COMPANY, Appellees

Appeal No. 83-1178

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

730 F.2d 1452; 1984 U.S. App. LEXIS 14874; 221 U.S.P.Q. (BNA) 481

March 21, 1984

PRIOR HISTORY: [**1]

Appealed from: District Court for the Southern District of Texas.

DISPOSITION:

REVERSED and REMANDED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant sought review of judgment of the District Court for the Southern District of Texas, sitting without a jury and holding invalid under *35 U.S.C.S. § § 102*(b), 103, and 112, three claims of appellant's patent in appellant's suit against appellees for patent infringement.

OVERVIEW: Appellant sued appellees for patent infringement. Appellees asserted non-infringement and counterclaimed for declaratory judgment that patent was invalid. Lower court ruled patent invalid, and appeal followed. Court held lower court's finding of anticipation under *35 U.S.C.S. § 102*(b) was mistaken and clearly erroneous since its analysis treated claims as mere catalogs of separate parts, in disregard of part-to-part relationship in claims that gave the claims their meaning. Lower court further erred when it viewed statutory presumption of validity, *35 U.S.C.S. § 282*, as "vanished" or "severely weakened" where appellees introduced prior art not cited by examiner; when it reduced required burden of proof to mere preponderance; and when it implicitly required appellant to prove uncited art had been considered by Patent and Trademark Office. Lower court also erred in finding claims' inventions would have been obvious under *35 U.S.C.S. § 103* and in finding patent specification was non-enabling under *35 U.S.C.S. § 112*.

OUTCOME: Court reversed finding that appellant's patent claims were invalid, holding lower court erred in finding inventions set forth in claims was anticipated by another patent, erred in finding invention was obvious, and erred in finding patent specification non-enabling. Case was remanded for lower court to make a finding on infringement.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Patentable Subject MatterPatent Law > Infringement > Burdens of Proof

[HN1] The court's role in relation to patentability does not require it to conclude whether something was or was not invented, or whether the court subjectively considers the invention worthy of patent protection. The court's role is actually more simple. Under the statute, it is to determine whether the patent's challenger carried the burden of establishing invalidity. *35 U.S.C.S. § 282*.

Patent Law > Novelty & AnticipationPatent Law > Jurisdiction & Review > Standards of Review

[HN2] Anticipation is a factual determination, reviewable under the clearly erroneous standard.

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous ReviewPatent Law > Jurisdiction & Review > Standards of Review

[HN3] A finding is clearly erroneous when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.

Patent Law > Novelty & Anticipation
[HN4] Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference.

Patent Law > Infringement > DefensesPatent Law > Infringement > Burdens of Proof
[HN5] The burden upon the challenger of validity under *35 U.S.C.S. § 282* is to introduce evidence of facts establishing invalidity, thus overcoming the presumption. That evidence, if it is to carry the day, must be clear and convincing.

Patent Law > Infringement > DefensesPatent Law > Infringement > Burdens of Proof
[HN6] To the extent that the examiner's consideration of uncited art is material, the burden is on the challenger to show that that prior art had not been considered. The challenger meets that particular burden by showing that the uncited art is more relevant than that cited, just as the patentee defeats the uncited art by showing that its relevancy is equal to or less than that cited.

Patent Law > Novelty & Anticipation
[HN7] The scope of the prior art is defined as that reasonably pertinent to the particular problem with which the inventor was involved.

Patent Law > Statutory BarsPatent Law > Nonobviousness > Tests & Proof of Obviousness
[HN8] A showing of commercial success of a claimed invention, wherever such success occurs, is relevant in resolving the issue of non-obviousness.

COUNSEL:

David Toren, of New York, New York, argued, for Appellant. With him on the brief was Jules Goldberg.

Michael E. Macklin, of Houston, Texas, argued, for Appellees. With him on the brief was Edward W. Goldstein.

JUDGES:

Markey, Chief Judge, Cowen, Senior Circuit Judge, and Bennett, Circuit Judge.

OPINIONBY:

MARKEY

OPINION:

[*1455] MARKEY, Chief Judge.

Appeal from the May 23, 1983, judgment of the District Court for the Southern District of Texas, sitting without a jury and holding invalid claims 1, 2, and 4 of appellant's (Lindemann's) U.S. Patent No. *3,945,315* issued March 23, 1976 and entitled "Hydraulic Scrap Shearing Machine". We *reverse* and *remand.*

BACKGROUND

The Patent

United States Patent No. *3,945,315* (*'315*) issued March 23, 1976 on an application filed April 16, 1975. Peter Dahlem and Hubert Milles are named co-inventors and Lindemann is listed as the assignee. The *'315* patent claims a priority filing date, under *35 U.S.C. § 119,* of May 13, 1974, based on West German application 2423003.

Hydraulic scrap shears, the subject matter of the *'315* patent, [**2] are a principal tool of the scrap metal industry. The shears are large, often weighing several hundred tons, and are designed to cut scrap metal into smaller, uniform pieces for recycling.

There are two basic types of metal processed in the shears: "peddler's scrap" and "rigidly massive scrap".

Peddler's scrap consists of light to medium gauge metal objects, such as light tubing, automobile bodies, and window frames. It makes up a large percentage of the available scrap and is comparatively easy to process.

Rigidly massive scrap consists of heavy gauge metal objects, such as boilers, oil tanks, and railroad cars. Because of thickness or internal reinforcements, massive scrap objects are difficult to process. Traditionally, massive scrap had been processed in very large, tremendously powerful shears, or had been pretreated, e.g., with oxyacetylene torches, to reduce its size or weaken its internal reinforcements. Either approach was costly and time-consuming. Many scrap dealers handled peddler's scrap exclusively.

The Invention

The *'315* patent contains five claims. Claim 1, the only independent claim, is written in Jepson form:

> 1. In a hydraulic scrap-shearing [**3] machine comprising an open feed channel having two opposing side walls, scrap shears at one end of said feed channel and having a mouth narrower than the normal width of said feed channel between said side walls, hydraulic means for moving at least one of said side walls towards the other of said side walls whereby scrap placed in said feed channel can be squashed to a final width no greater than the width of said mouth of said scrap shears, and a feeder ram for pushing scrap along said feed channel into said mouth of said scrap shears, the improvement consisting of said movable one of said side walls being divided into two longitudinal portions of different lengths, and said hydraulic means comprising a main hydraulic ram having a working face forming the longer portion of said movable side wall, and an auxiliary hydraulic ram having a working face forming the shorter portion of said movable side wall just upstream of said mouth of said scrap shears, said auxiliary hydraulic ram being capable of operation independently of said main hydraulic ram.

The claimed structure is shown in Figure 2 of the *'315* patent:

[*1456] [SEE ILLUSTRATION IN ORIGINAL]

In operation, [**4] the combined rams (17, 19) advance into the feed channel (9), crushing and compacting the scrap (12) against the other, non-movable sidewall (14). With peddler's scrap, the two rams move the entire distance together. However, when the channel contains rigidly massive scrap, such as shown at (12), the two rams are quickly brought to a standstill by the scrap's resistence to crushing. The auxiliary ram (19) is then moved forward independently of the main ram (17). The auxiliary ram, having a smaller working surface than the combined rams, is capable of applying a greater crushing force to the scrap. The auxiliary ram cracks and buckles the scrap directly in front of it to crush the leading end of the scrap so it can be pushed through the mouth of the shears. That action also propagates that effect to an adjacent area (H) of the scrap. The structural integrity of the scrap is thus overcome by the auxiliary ram, thereby reducing the resistance of the portion of the scrap in contact with the main ram, allowing both rams to continue forward to crush the scrap to a width less than that of the shear mouth. The feeder ram (11) then pushes the crushed scrap through the mouth of the shear [**5] and under the shear blades (at 5) and clamp (at 6). The clamp holds the crushed scrap in place during cutting.

The claimed invention allows one machine of moderate size to process both peddler's and rigidly massive scrap, and to do so quickly, inexpensively, and without the need for pre-treating massive scrap. Unchallenged testimony described crushing accomplished in minutes of scrap that would have required hours to crush in earlier larger machines and that could not have been crushed without pretreatment.

District Court Proceedings

On October 5, 1980, Lindemann sued appellees (collectively "Amhoist") for infringement of claims 1, 2, and 4 of the *'315* patent. Amhoist asserted non-infringement and counterclaimed for a declaratory judgment that the *'315* patent is invalid.

A three day trial was conducted on June 21-23, 1982. On May 23, 1983, the district court entered FINDINGS OF FACT AND CONCLUSIONS OF LAW, the introduction of which stated:

> After hearing all the evidence the Court concludes that the patent is invalid. Plaintiff simply incorporated two admittedly well-known metal compression features in the same machine and sought to gain a monopoly in the use [**6] of knowledge [*1457] that had previously existed in the public domain. The Court finds and concludes that the claimed invention of the Plaintiff does not meet the statutory or constitutional requirements established for patent protection. Specifically, the machine was an obvious aggregation of prior art which produced no new or synergistic result. It failed materially to promote the progress of science and the useful arts.

The district court entered 60 findings and 20 conclusions indicating its view that the *'315* patent is invalid under *35 U.S.C. § 102*(b), *35 U.S.C. § 103,* and *35 U.S.C. § 112.*

On May 24, 1983 the district court entered judgment declaring the *'315* patent invalid. The judgment is silent respecting infringement, though the district court had stated from the bench at end of trial:

> Well, if the *'315* patent is valid, I think the proof is clear that it has been infringed and it is pretty clear that it was done with

knowledge, conscious knowledge to the point of willful infringement. n1

n1 The district court stated at the same time, "But I am not certain in my own mind at this point whether or not these gentlemen on the *'315* patent invented anything". The statement reflects a misconception of the role of the courts under *35 U.S.C. § 103.* The question mandated by statute is not "invention"; it is *patentability. See Rich, Escaping the Tyranny of Words -- Is Evolution in Legal Thinking Impossible?, 60 JPOS 71,* May-June/APLA Bull. 237 (1978).

Moreover, [HN1] the court's role in relation to patentability does not require it to conclude whether something was or was not "invented", or whether the court subjectively considers the invention "worthy" of patent protection. The court's role is actually more simple. Under the statute, it is to determine whether the patent's challenger carried the burden of establishing invalidity. *35 U.S.C. § 282. See Environmental Designs, Ltd. v. Union Oil Co. of Cal., 713 F.2d 693, 218 USPQ (BNA) 865 (Fed. Cir. 1983), Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 USPQ (BNA) 871 (Fed. Cir. 1983), Rosemount, Inc. v. Beckman Instruments, 727 F.2d 1540 (Fed. Cir. 1984).*

[**7]

Issues

I. Whether the district court erred in finding the inventions set forth in claims 1, 2, and 4 anticipated by U.S. Patent *3,763,770* (*'770*) under *35 U.S.C. § 102*(b).

II. Whether the district court erred in concluding that the inventions set forth in claims 1, 2, and 4 would have been obvious under *35 U.S.C. § 103.*

III. Whether the district court erred in concluding that the *'315* patent specification was non-enabling under *35 U.S.C. § 112.*

IV. Whether this court on remand should order entry of a judgment that claims 1, 2, and 4 were infringed by Amhoist.

OPINION

Of the district court's 60 findings, 57 were those submitted by Amhoist before trial. The source of findings does not render the "clearly erroneous" standard of Fed.R.Civ.P. 52(a) any less applicable or binding. *Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, n.4 (Fed. Cir. 1984).* In adhering firmly to that rule, however, an apparent absence of personal attention need not be disregarded. *See Amstar Corporation v. Domino's Pizza, Inc., 615 F.2d 252, 258, 205 U.S.P.Q. (BNA) 969, 974 (5th Cir. 1980), Wilson v. Thompson, 593 F.2d 1375, 1384 n.16 (5th Cir. 1979).* Under such [**8] circumstances, one court has indicated that strict scrutiny is appropriate. *See Smith International, Inc. v. Hughes Tool Co., 664 F.2d 1373, 215 U.S.P.Q. (BNA) 592 (9th Cir. 1982).* Where, as here, the adopted findings are those proposed by a party *before trial*, a greater chance is created that those findings may be clearly erroneous. Indeed, the present findings include some for which no supporting evidence was submitted at trial.

Having written them, Amhoist argues strenuously for retention of the findings behind the shield of the "clearly erroneous" rule, and repeatedly reminds us of our duty to review the findings favorably and of the burden resting on the appellant. [*1458] However salutary, the rules governing review do not envision an appellate court shirking its duty to reverse an appealed judgment that is clearly based on legal error and unsupported by evidence in the record.

We review judgments, not the rhetoric in opinions. Nonetheless, the language in an opinion, or in a set of findings and conclusions, may indicate that numerous harmful errors of law produced an erroneous conclusion, and that the decisional approach of the district court led to a judgment [**9] not supported in law by the facts of record. That happened here.

I. *Anticipation*

[HN2] Anticipation is a factual determination, reviewable under the "clearly erroneous" standard. *Carman Industries Inc. v. Wahl and Vibra Screw Inc., 724 F.2d 932 (Fed. Cir. 1983), Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 218 U.S.P.Q. (BNA) 781 (Fed. Cir. 1983),* F.R.C.P. 52(a). "A [HN3] finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed". *United States v. U.S. Gypsum Co., 333 U.S. 364, 395, 92 L. Ed. 746, 68 S. Ct. 525, 76 U.S.P.Q. (BNA) 430, 444 (1948); SSIH Equip. S.A. v. USITC, 718 F.2d 365, 381, 218 U.S.P.Q. (BNA) 678, 692 (Fed. Cir. 1983).*

[HN4] Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 U.S.P.Q. (BNA) 193 (Fed. Cir. 1983); SSIH Equip. S.A. v. USITC, 718 F.2d 365, 218 U.S.P.Q. (BNA) 678 (Fed. Cir. 1983).* In deciding the issue of anticipation, the trier of fact [**10] must identify the elements of the claims,

determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman, supra.*

Lindemann contends the district court's finding on anticipation is clearly erroneous and we agree.

The finding of anticipation rested on a series of mistakes. The two gags of the *'770* patent do not correspond to "said sidewall being divided into two portions of different lengths". The gags are beyond the end of the wall and constitute no part of a feed channel sidewall as claimed. The court found the *'770* patent's magazine corresponded to the claimed "open feed channel having two opposing walls", but the "movable" wall of the magazine is movable only to adjust the magazine's width and not, as the claim requires, to crush scrap. Moreover, the findings that the magazine is the feed channel and that the gags are parts of a sidewall of the channel contradict each other. Nor does the shear anvil of the *'770* patent, as the court stated, correspond to the "opposite sidewall" of the claim. Nor do the cylinder assemblies of the *'770* patent move [**11] one sidewall of a feed channel toward the other as the claims require. Nor are the *'770* patent's cylinder and gag (equated by the court to the claimed auxiliary ram) located "just upstream of said mouth". They are within the shear area and are thus downstream from where a mouth narrower than the feed channel would be if the *'770* patent disclosed such a mouth, which it does not. Similarly, the other cylinder and gag of the *'770* patent do not form a "longer portion of said movable sidewall". Nor can the channel that receives rod cuttings after shearing be equated, as did the district court, with the shear mouth claimed. n2

> n2 Amhoist says Lindemann's Australian counsel "conceded" that the *'770* patent cited by the Australian examiner was a "paper anticipation". The assertion is meaningless. First, the *'315* patent's counterpart issued in Australia. Second, the language and laws of other countries differ substantially from those in the United States.

The *'770* patent discloses an entirely different device, [**12] composed of parts distinct from those of the claimed invention, and operating in a different way to process different material differently. Thus there is presented here no possible question of [*1459] anticipation by equivalents. *See Tate Engineering, Inc. v. United States, 201 Ct. Cl. 711, 477 F.2d 1336, 1342, 175 U.S.P.Q. (BNA) 115, 119 (1973).* It is clear, moreover, that the device disclosed in the *'770* patent, had it come after issuance of the *'315* patent, could not be found an infringement of the asserted claims. The district court's analysis treated the claims as mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning.

On the unchallenged evidence of record, we are left with a "definite and firm conviction" that the district court's finding of anticipation was mistaken and therefore clearly erroneous. That part of its judgment relating to invalidity under *35 U.S.C. § 102*(b) must therefore be reversed.

II. *Obviousness*

A. *Presumption of Validity*

Guided by remarks found in then applicable court opinions, the district court: (1) viewed the statutory presumption [**13] of validity, *35 U.S.C. § 282,* as "vanished" or "severely weakened" when Amhoist introduced prior art not cited by the examiner; (2) reduced the required burden of proof, in light of that introduction, to a "mere preponderance" n3; and (3) implicitly required Lindemann to prove that the uncited art had been considered by the PTO.

> n3 The district court in a conclusion of law also stated that "under any burden of persuasion the *'315* patent is invalid because of obviousness". As indicated in the text, we disagree.

(1) Courts are not, of course, at liberty to repeal a statute, or to legislate conditions diminishing its effect. Hence the statutory presumption cannot "vanish" or be "weakened" and the statutorily assigned burden of proof cannot be shifted. *Stratoflex Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 U.S.P.Q. (BNA) 871 (Fed. Cir. 1983).* At the same time, much confusion can be avoided by patentees who refrain from efforts to expand the role of the presumption beyond its burden-assigning and decisional [**14] approach-governing function.

(2) [HN5] The burden upon the challenger of validity under *35 U.S.C. § 282* is to introduce evidence of facts establishing invalidity (thus overcoming the presumption). *American Hoist & Derrick Company v. Sowa & Sons, Inc., 725 F.2d 1350 (Fed. Cir. 1984).* That evidence, if it is to carry the day, must be clear and convincing. *Radio Corp. v. Radio Laboratories, 293 U.S. 1, 79 L. Ed. 163, 54 S. Ct. 752 (1934).* Because the mere introduction of non-considered art (a common phenomenon) does not "weaken" or otherwise affect the presumption, there is no basis for adjusting the required

level of proof downward to a "mere preponderance". That the clear and convincing standard may more easily be met when such non-considered art is *more* pertinent than the cited art means that determination of whether the patent challenger has met its burden turns on the relationship of the uncited art to the claimed invention. *Stratoflex, supra; Railroad Dynamics Inc. v. A. Stucki Co., 727 F.2d 1506 (Fed. Circ. 1984), Solder Removal v. USITC, 65 C.C.P.A. 120, 582 F.2d 628, 199 U.S.P.Q. (BNA) 129 (1978).*

(3) Similarly, the parties have devoted much unnecessary [**15] argument to the question of whether Lindemann is entitled to a presumption that the examiner had considered the uncited art because it is found in the classes and subclasses searched by the examiner (and because, as Lindemann says, the examiner had cited that art in examining an earlier application). Authorities are cited on both sides. n4

n4 The district court indicated the view that "the 'Field of Search' is exactly what it purports to be and nothing more, that 'References Cited' are the patents found within the field which were actually considered by the examiner and listed because he found them to be most relevant". That view is flawed. The examiner could not determine which patents are "most relevant" without considering a number which are less relevant.

Because the touchstone is whether the uncited art is sufficiently more relevant than that cited to serve as evidence of obviousness, argument respecting [*1460] a presumption based on the uncited art's classification is pointless. The argument [**16] here, moreover, appears to have led to the erroneous view that Lindemann bore the burden of proving that the uncited art had been considered. [HN6] To the extent that the examiner's consideration of uncited art is material, the burden is on the challenger to show that "that prior art had *not* been considered." *Richdel Inc. v. Sunspool Corp., 714 F.2d 1573, 219 U.S.P.Q. (BNA) 8 (Fed. Cir. 1983).* The challenger meets that particular burden by showing that the uncited art is more relevant than that cited, just as the patentee defeats the uncited art by showing that its relevancy is equal to or less than that cited. n5

n5 Though the courts will give due respect to the examiner's evaluation of prior art, they are not of course bound thereby. Patentees desiring the benefit of the examiner's evaluation of originally uncited art have available the reexamination procedures under *35 U.S.C. § § 301*-307. Those procedures were not employed in this case.

B. *Scope and Content of the Prior Art* n6

n6 The level of skill is not of record and is not discussed in the briefs.

----------End Footnotes----------

[HN7] - [**17]

"The scope of the prior art has been defined as that 'reasonably pertinent to the particular problem with which the inventor was involved'." *Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 U.S.P.Q. (BNA) 871, 876 (Fed. Cir. 1983)* (and cases cited therein). The district court defined the problem here broadly, i.e., as the problem of compressing waste materials. That finding is clearly erroneous. The inventors' problem was the crushing of massive metal scrap. Nothing in the prior art relied on as invalidating had any relation whatever to the crushing of massive metal scrap.

Lindemann attempts too much in arguing that waste compactors are non-analogous. Though the problems differ, both parties manufacture both products and both are exhibited at the same trade shows. Art that is analogous may or may not render a claimed invention obvious. As indicated below, it does not do so here.

The content of the prior art discussed in Amhoist's brief is that disclosed in the *'770* patent (discussed above) and in British Patent No. 1,230,014 ('014). n7

n7 The district court additionally discussed the S-501 shear produced by Amhoist and incorporating a tapered feed channel with a single side ram about one foot from the shear mouth. Amhoist correctly recognizes on appeal the absence of need to discuss the S-501 shear.

[**18]

The '014 patent discloses a compactor for particulate waste, e.g., garbage. The loose waste is pressed into the wide mouth of a funnel by a circular plate. The smaller end of the funnel communicates with a container to receive the compacted waste. A small finger-like ram is coaxial with, and normally moves with, the plate. When the material fills the funnel so tightly that the plate can add no more, the separately operable small ram can be advanced ahead of the main ram and into the waste material. The small ram has a diameter smaller than that of the funnel outlet. When the small ram has pressed a

core of waste material through the funnel outlet, the remaining waste material is loosened and additional waste material may then be pressed into the funnel by the plate and ram working together.

In a conclusion of law, the district court stated that it had considered the facts in light of the inquiries mandated by *Graham v. John Deere & Co., 383 U.S. 1, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966),* and that a strong indication supporting its conclusion of obviousness was "the fact that three individuals independently created the designs which resulted in development of the split [**19] ram shears which are the subjects of this lawsuit". Because the statute, *35 U.S.C. § 135,* (establishing and governing interference practice) recognizes the possibility of near simultaneous invention by two or more equally talented inventors working independently, that occurrence may or may not be an indication of obviousness when considered in light of all the circumstances. *See E.I. DuPont de* [*1461] *Nemours & Co. v. Berkley & Co., 620 F.2d 1247, 205 U.S.P.Q. (BNA) 1 (8th Cir. 1980).* In this instance, it clearly is not. Two of the three individuals were Dahlem and Milles, the co-inventors listed on the *'315* patent. The third was an Amhoist employee who claimed at trial to have proposed the split ram in January of 1979, more than five years after the invention was made by Lindemann's assignors, nearly three years after the *'315* patent issued, and well after Amhoist's employee Bleeland had in England observed and photographed a Lindemann shear embodying the claimed invention. Accepting, as we must, the district court's crediting of the testimony respecting independent suggestion by an Amhoist employee, that suggestion was simply too late to have been relevant to a determination [**20] of whether the invention would have been obvious at the time it was made, *35 U.S.C. § 103,* which was more than five years earlier.

C. *Commercial Success.*

The district court improperly discounted the weight due the evidence of commercial success because that success occurred abroad. [HN8] A showing of commercial success of a claimed invention, wherever such success occurs, is relevant in resolving the issue of non-obviousness. *Weather Engineering Corp. v. United States, 222 Ct. Cl. 322, 614 F.2d 281, 204 USPQ 41 (1980).*

The evidence at trial showed that the claimed invention accounted for 30% of Lindemann's total sales worldwide for a total sales price of over $20,000,000 (30 machines at approximately $667,000 each). The district court correctly stated that commercial success cannot by *itself* establish nonobviousness. However, having concluded that the claimed invention would have been obvious from the prior art, the court looked only to see whether the showing of commercial success was so overwhelming as to overcome that conclusion. That was error. All evidence must be considered *before* a conclusion on obviousness is reached. *Stratoflex, Inc. v. Aeroquip* [**21] *Corp., 713 F.2d 1530, 218 U.S.P.Q. (BNA) 871 (Fed. Cir. 1983), Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 219 U.S.P.Q. (BNA) 857 (Fed. Cir. 1983), W. L. Gore & Associates v. Garlock, Inc., 721 F.2d 1540, 220 U.S.P.Q. (BNA) 303, 314 (Fed. Cir. 1983).* The commercial success here shown is evidence that the claimed invention was not obvious to those who paid 2/3 of a million dollars for each machine to escape the previously perceived need for pretreatment of massive scrap.

D. *Unexpected Results*

The district court ignored the unexpected or surprising results achieved by the claimed invention. Though no requirement for such results is present in the statute, *35 U.S.C. § 103, Chore-Time Equipment, Inc. v. Cumberland Corp., 713 F.2d 774, 218 U.S.P.Q. (BNA) 673 (Fed. Cir. 1983),* evidence of unexpected results may be strong support for a conclusion of nonobviousness. *Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 219 U.S.P.Q. (BNA) 857 (Fed. Cir. 1983).*

Neither the district court nor Amhoist's brief on appeal has a word to say about the unexpected results asserted by Lindemann, namely, the rapid crushing of rigidly massive scrap in a moderate sized scrap shear without [**22] pretreatment. That the claimed inventions achieve those results is unchallenged. Neither the district court nor Amhoist suggest anything in any piece of prior art, or in the prior art as a whole, that would lead one skilled in the art to expect achievement of such results.

The record is clear that no earlier shears of any size, and no prior art device of any type could economically process rigidly massive scrap without pretreatment. Unchallenged testimony of experts was characterized by surprise and amazement that the claimed invention was able to accomplish that feat. That it could do so in minutes, and with a moderate sized structure, were further sources of surprise. That those skilled in the art had previously believed pretreatment of rigidly massive scrap was required was also uncontradicted.

[*1462] It is further clear from the uncontradicted evidence that the claimed invention achieved new and unexpected results nowhere suggested in the prior art, and that the district court overlooked the effect of that achievement in reaching its determination of obviousness. In so doing, the district court erroneously focussed its inquiry "solely on the product created, rather

[**23] than on the obviousness or nonobviousness of its creation". *General Motors Corp. v. U.S. International Trade Commission, 69 C.C.P.A. 116, 687 F.2d 476, 482-83, 215 U.S.P.Q. (BNA) 484, 489 (1982).*

The district court viewed the claimed invention as merely the "aggregation" of two different sized rams. Finding the first in one place in the prior art and the second in another place, the district court entered this conclusion:

> Plaintiff simply put the two features in the same machine and connected them as was necessary depending on whether the scrap was small or large. It used a known connection idea. The *'315* machine possessed one known feature to operate in a known way to produce a known result to deal with the first scrap situation and another known feature operating in a known manner to produce a known result to deal with the second. Clearly, this was an obvious solution using already appreciated or obvious features to solve the problem of how to develop a machine that could handle both types of scrap most economically.

The *'315* patent specifically stated that it disclosed and claimed a combination of features previously used in two separate devices. That [**24] fact alone is not fatal to patentability. The claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. *In re Imperato, 486 F.2d 585, 179 U.S.P.Q. (BNA) 730 (CCPA 1973); In re Sernaker, 702 F.2d 989, 217 U.S.P.Q. (BNA) 1 (Fed. Cir. 1983).* That question must here be answered in the negative.

Nothing in the references alone or together suggests the claimed invention as a solution to the problem of crushing rigidly massive scrap. There was nothing whatever of record, therefore, to support the district court's statement that the claimed machine possessed "another known procedure operating in a known manner to produce a known result" or its conclusion that Lindemann "knew . . . that a small sidewall ram could most economically process large scrap".

The '014 patent deals only with soft, easily compactible, particulate material. Though that patent discloses a two-ram structure and the principle that loose material when too tightly compacted can be loosened by injection of a thin ram into the material, the claims here are not drawn [**25] to the mere concept of two differently sized rams, or to the known principles governing the effects of large and small rams (or to the propagation of force principle discussed at trial). That the claimed invention may employ known principles does not in itself establish that the invention would have been obvious. Most inventions do. Nothing in the '014 patent would suggest that rigidly massive scrap could be rapidly and economically crushed and sheared without pretreatment.

The *'770* patent, as above indicated, deals only with holding brittle material within a shear by compression. Nothing in the *'770* patent suggests that making the crushing wall of a metal scrap shear in two independently operable parts, with a smaller part adjacent the mouth of the shears, would enable the crushing of massively rigid scrap without pretreatment.

Nothing, moreover, in the '014 or *'770* patents adds anything to the prior art considered by the examiner. As above indicated, the *'315* specification itself recognized the separate presence in the prior art of feed channels with one solid moveable crushing wall and of feed channels with a small ram in one of two fixed sidewalls. The examiner cited [**26] as "of interest" the Pioch patent which, like the '014 patent, [*1463] disclosed two independently operable pushers in a waste compactor.

Applying the standard of Rule 52(a), Fed. R. Civ. P., we are persuaded that the findings underlying the district court's conclusion of obviousness are clearly erroneous. Further, that conclusion resulted from errors of law in interpreting the claims and in consideration and application of the prior art. That part of the appealed judgment relating to *35 U.S.C. § 103* must therefore be reversed.

III. *Enablement*

The district court concluded that the *'315* patent was non-enabling because it did not disclose a hydraulic and electrical system for controlling the operation of the rams.

Enablement is a legal issue. *Raytheon Co. v. Roper Corp., 724 F.2d 951 (Fed. Cir. 1983).* The question is whether the disclosure is sufficient to enable those skilled in the art to practice the claimed invention, hence the specification need not disclose what is well known in the art. *In re Myers, 56 C.C.P.A. 1129, 410 F.2d 420, 161 U.S.P.Q. (BNA) 668 (1969).*

The unchallenged evidence of record establishes that hydraulic and electrical systems [**27] for metal scrap shears were well known to those skilled in the art, and that the selection and connection of the elements of such systems was simply a matter of plumbing.

Amhoist points to testimony relating to 800 man hours it expended in developing its split ram shear. It also points to the dismantling of the accused machines by its two customers, whereby the rams are operated together as one sidewall and asserts that the split ram structure of the claimed invention has thus been abandoned by those customers. n8 There is no evidence indicating that the dismantling was due to difficulty in designing a suitable hydraulic-electric control system.

n8 The record does not reflect the rationale underlying a vigorously fought lawsuit and its accompanying expense in the light of two sales and both purchasers' cessation of use of the invention.

It is clear that no undue experimentation was required in practicing the claimed invention. *W.L. Gore & Assoc. Inc. v. Garlock, Inc., 721 F.2d 1540, 1557, 220 USPQ* [**28] *(BNA) 303, 316 (Fed. Cir. 1983).* Amhoist spent approximately 100 more hours than did Lindemann in designing the entire split ram shear, including the hydraulic-electric control system. There was no evidence of the amount of time needed to develop the control system itself. Of the total time Amhoist spent on developing its shear, it devoted an undisclosed amount attempting to create a "hydraulically operated pin" to connect the two rams. That pin was unnecessary. The *'315* patent's specification discloses a simple mechanical pin to achieve the same connection. Further, Amhoist conceded at oral argument that nothing in the claims fails of enablement in the specification.

The district court erred in its conclusion that the *'315* patent specification is non-enabling and that part of the appealed judgment relating to *35 U.S.C. § 112* must be reversed.

IV. *INFRINGEMENT*

Relying on the statement made by the district court at close of trial, and on the uncontested evidence clearly establishing Amhoist's knowledge of the *'315* patent and its conscious decision to disregard it, Lindemann requests this court to "affirm" the district court's "decision" on infringement. Lindemann's [**29] difficulty is that judgments, not statements, are appealed and the district court made no finding and entered no judgment on infringement.

A district court should decide validity and infringement and should enter a judgment on both issues when both are raised in the same proceeding. *Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 U.S.P.Q. (BNA) 871 (Fed. Cir. 1983).* To enter judgment on less than all dispositive issues can be inefficient, risking as it does the necessity of the district court and the parties [*1464] undertaking participation in another long and costly proceeding.

The case must be remanded for the district court to make a finding on infringement. Whether the present record supports a finding corresponding with the court's end-of-trial statement, and whether further trial on the issue is therefore unnecessary, is for the district court to determine in the first instance. Upon any finding of infringement and entry of judgment on that finding, the district court will doubtless consider issuance of an injunction against further infringement and an accounting.

DECISION

The district court's judgment is reversed and the case is remanded for further [**30] proceedings consistent with this opinion.

REVERSED and REMANDED

LEXSEE

ALCO STANDARD CORPORATION, an Ohio corporation, Appellee, v. TENNESSEE VALLEY AUTHORITY, a U.S. corporation, and WESTINGHOUSE ELECTRIC CORPORATION, a Pennsylvania corporation, Appellants

No. 85-2420

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

808 F.2d 1490; 1986 U.S. App. LEXIS 20930; 1 U.S.P.Q.2D (BNA) 1337

December 30, 1986, Decided

PRIOR HISTORY: [**1]

Appealed from U.S. District Court for the Western District of Tennessee, Judge Horton.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellants, a United States corporation and its indemnitor, appealed a judgment of the United States District Court for the Western District of Tennessee, holding appellee corporation's patent covering a method of and apparatus for inspecting turbine rotors valid and infringed.

OVERVIEW: Appellee corporation held a patent covering a method of and apparatus for inspecting turbine rotors. Appellee alleged that appellants, a United States corporation and its indemnitor, were liable for patent infringement, and the district court agreed. The court affirmed, holding that it had jurisdiction under *28 U.S.C.S. § § 1295*(a)(1) and 1338(a) to hear the appeal, since the district court exercised its jurisdiction on the basis of an Act of Congress "relating to patents." Furthermore, the district court properly ruled that the invention of appellee's patent was not obvious, where strong evidence of secondary considerations established that the invention, which appeared to have been obvious in light of the prior art, was not. Specifically, the invention was a commercial success that fulfilled long-felt but unresolved needs in a field where others had failed. Although the evidence of infringement was circumstantial, such evidence was not any less credible or persuasive.

OUTCOME: The court affirmed the district court's judgment that the claims of appellee's patent were valid and enforceable and that appellants were liable for infringement of those claims, since appellants did not show that the district court's findings were clearly erroneous, and the district court's errors were harmless.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction
[HN1] Under *28 U.S.C.S. § § 1295*(a)(1) and 1338(a), the United States Court of Appeals for the Federal Circuit has jurisdiction over an appeal from a district court if the jurisdiction the district court exercised was based upon an Act of Congress "relating to patents."

Patent Law > Jurisdiction & Review > Standards of Review
[HN2] The reviewing court's role is to determine whether the district court committed any reversible errors, either in its factual findings or in its legal conclusions or rulings, not to decide the case de novo.

Patent Law > Specification & Claims > Enablement RequirementPatent Law > Specification & Claims > Description Requirement
[HN3] See *35 U.S.C.S. § 112.*

Patent Law > Originality > Joint & Sole Inventions
[HN4] The inclusion in a patent of a process that may be performed by a person, but that also is capable of being performed by a machine, is not fatal to patentability.

Patent Law > Novelty & Anticipation
[HN5] Under *35 U.S.C.S. § 102*(a), a patent is invalid if the invention was described in a printed publication in the United States before the invention thereof by the applicant for patent. Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.

Patent Law > Nonobviousness > Tests & Proof of ObviousnessPatent Law > Infringement > DefensesPatent Law > Infringement > Burdens of Proof
[HN6] The existence of uncited prior art more relevant or more pertinent than the art called to the attention of the Patent Office does not weaken the statutory presumption that a patent is valid pursuant to *35 U.S.C.S. § 282.* It merely makes it easier for the party challenging the validity of the patent to carry his burden of proof.

Patent Law > Infringement > DefensesPatent Law > Infringement > Burdens of Proof
[HN7] The presumption of a patent's validity may be rebutted only by clear and convincing evidence.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN8] The criteria for determining obviousness are (i) the scope and content of prior art, (ii) differences between the claims of a patent and the prior art, and (iii) the level of ordinary skill in the pertinent art. Secondary considerations relating to obviousness include commercial success, long-felt but unsolved needs, and failure of others.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN9] In evaluating the scope and content of prior art and the differences between that art and the claims of a patent, the question is not simply whether the prior art "teaches" the particular element of the invention, but whether it would suggest the desirability, and thus the obviousness, of making the combination.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN10] Prior art cannot be evaluated in isolation, but must be considered in the light of the secondary considerations bearing on obviousness.

Patent Law > Infringement > Acts of Infringement
[HN11] Although evidence of infringement may be circumstantial, that does not make it any less credible or persuasive.

COUNSEL:

John F. Lynch, for Appellants. With him on the brief was Alan H. Gordon.

Gomer W. Walters, for Appellee. With him on the brief were Rolf O. Stadheim, John W. Hofeldt.

JUDGES:

Friedman, Rich, and Nies, Circuit Judges. Nies, Circuit Judge, concurring. Rich, Circuit Judge, dissenting.

OPINIONBY:

FRIEDMAN

OPINION:

[*1492] FRIEDMAN, Circuit Judge.

This is an appeal from the judgment of the United States District Court for the Western District of Tennessee, *597 F. Supp. 133,* in a patent infringement suit holding U.S. Patent No. *3,960,006* (*'006* patent) valid and infringed. The case was tried to the court, which decided only the liability and not the damages issue. We affirm.

The plaintiff below and the appellee here is Alco Standard Corporation (Alco), which acted through its Commercial Machine Works division (Commercial). The nominal defendant below and an appellant here is the Tennessee Valley Authority (TVA). The defendant real party in interest is the third party defendant, and co-appellant here, Westinghouse Electric Corporation (Westinghouse), which performed [**2] services involving the patented invention for TVA and agreed to indemnify TVA for any damages arising from those services.

Prior to trial, the court dismissed Alco's patent infringement claims against Westinghouse. *Alco Standard Corp. v. Tennessee Valley Authority, 448 F. Supp. 1175 (W.D. Tenn. 1978).* Westinghouse remained in the case, as the indemnitor of TVA, and has conducted the defense of this suit.

I

Background

A. The *'006* patent covers a method of and apparatus for inspecting turbine rotors in electrical generators by the use of ultrasonic waves to detect discontinuities within the rotors. Discontinuities are cracks, flaws, or impurities and may result when the rotors are made or may develop later with use. Turbine rotors are large cylindrical metal forgings which can be

as long as 30 feet and weigh as much as 100 tons. In operation, they may rotate at speeds as high as 3600 revolutions per minute and reach temperatures of 1000 degrees F. The high speeds and temperatures subject the rotor to stress, so that discontinuities in the turbine forging may cause it to fly apart.

As early as 1946, turbine rotor forgings were being inspected with ultrasonic [**3] tests. Such tests were performed from the outside of the forgings of newly manufactured rotors. In 1957, Westinghouse undertook a development program to improve its ultrasonic inspections. In 1959, Westinghouse discovered that General Electric Corporation was producing a new type of ultrasonic inspection, a boresonic testing device, that could be inserted into the bore of the rotor as distinguished from prior inspection devices that scanned only the outside of the rotor. Upon learning this, Westinghouse abandoned its development program, purchased the General Electric device and used it until 1972. The General Electric device, although providing for a bore inspection, could be used to inspect only newly manufactured rotors.

In the 1950's it became clear that a system for inspecting rotors that were not newly manufactured was needed because such rotors otherwise had to be removed from the turbine and shipped to the inspection site, causing costly delays. Apparently, General Electric solved this problem, and Westinghouse attempted to buy the new General Electric device in 1972. General Electric, however, refused to sell the new device, and therefore Westinghouse again began its own [**4] independent development program, this time to produce an on-site inspection device. Westinghouse's development of an on-site inspection device did not go as planned, and soon fell behind schedule.

[*1493] Also during 1972, Mr. Smith, an employee of Commercial, conceived the idea of producing a new type of boresonic test apparatus. In December 1972, Westinghouse officials, including a Mr. Ronca, visited Commercial to discuss Commercial's idea for such an apparatus. At that meeting, Mr. Ronca stated that he thought that Commercial's concept was not feasible because Westinghouse's own research and development in that area had been unsuccessful. Despite Westinghouse's skepticism, Commercial contracted to have the boresonic unit constructed.

In January 1974, Commercial demonstrated its boresonic device to Westinghouse. Among those Westinghouse representatives in attendance was Mr. Ronca, who, after witnessing the demonstration, wrote that the "system represent[ed] a significant advancement in the field of boresonics. . . ." Based on the Commercial demonstration, Westinghouse discontinued its research on boresonic devices and pursued the possibility of purchasing Commercial's [**5] device.

In mid-1974, a rotor in TVA's Gallatin steam plant exploded, causing substantial property damage and, luckily, no bodily injuries. Commercial inspected the remaining rotor at the Gallatin plant and discovered that it had a discontinuity similar to the one that caused the first rotor to explode. Subsequent remedial measures were taken to remove the discontinuity in the remaining rotor.

By October 1974, Westinghouse had abandoned its plan to purchase Commercial's boresonic units and had begun developing its own boresonic unit. It developed such a unit. Alco alleged that Westinghouse infringed the *'006* patent by using the Westinghouse device in inspecting TVA rotors.

B. The invention the *'006* patent covers was made by Robert Smith when he was an employee of Commercial. The patent issued on June 1, 1976, and was assigned to Alco.

In the present suit, Commercial alleged infringement of six claims of the *'006* patent. Three of these are apparatus claims and the other three are method claims.

Claim one, the broadest apparatus claim, is directed to a device for detecting discontinuities in a turbine rotor. The device has a probe that is inserted into the bore of a turbine [**6] rotor. Attached to this probe is an indexing means that determines the position of the probe within the rotor. The probe, itself, contains at least two ultrasonic sources (called "transducers") that simultaneously can send ultrasonic signals into the rotor. Any signals sent into the rotor that are reflected back to the probe are picked up by an ultrasonic pickup and recorded in such a manner that the "existence, position, nature, size and shape of the flaws in the rotor" can be determined.

The method claims generally describe a method for determining flaws within turbine rotors that utilizes the device described in the apparatus claims.

The claims are discussed in greater detail later in this opinion.

C. In a lengthy opinion, the district court held that the *'006* patent was valid and that Westinghouse had infringed the patent in using its own boresonic device to inspect TVA rotors. Specifically, the district court ruled that the Commercial invention was novel under *35 U.S.C. § 102* and non-obvious under *35 U.S.C. § 103.* The court also thoroughly examined whether Commercial had complied with the enabling, description, and definiteness [**7] requirements of *35 U.S.C. § 112* and found that it had. Regarding infringement, the

district court found that the "Westinghouse device contain[ed] every element found in claims 1, 2, 3, 7, 8 and 10 of the *006* patent."

II

Jurisdiction

[HN1] Under *28 U.S.C. § 1295*(a)(1) (1982), we have jurisdiction over this appeal from the district court if its jurisdiction "was based, in whole or in part, on section 1338 of this title . . . ." Section 1338(a) gives the [*1494] district courts "jurisdiction of any civil action arising under any Act of Congress relating to patents . . ." The inquiry thus is whether the jurisdiction the district court exercised in this case was based upon an Act of Congress "relating to patents."

The Tennessee Valley Authority Act of 1933 contains a specific provision dealing with patents. Section 831r of title 16 (1982) is captioned "Patents; access to Patent and Trademark Office and right to copy patents; compensation to patentees." It gives the Tennessee Valley Authority (TVA) access to the Patent and Trademark Office [**8]

> for the purpose of studying, ascertaining, and copying all methods, formulae, and scientific information (not including access to pending applications for patents) necessary to enable [TVA] to use and employ the most efficacious and economical process for . . . any method of improving and cheapening the production of hydroelectric power.

It then provides that

> any owner of a patent whose patent rights may have been thus in any way copied, used, infringed, or employed by the exercise of this authority by [TVA] shall have as the exclusive remedy a cause of action against [TVA] to be instituted and prosecuted on the equity side of the appropriate district court of the United States, for the recovery of reasonable compensation for such infringement.

The statute, in the second quoted passage, thus recognizes that the use by TVA of a patented invention constitutes infringement of the patent. Although the statute specifies that the patentee's "exclusive remedy" if its patent has been "thus . . . infringed . . ." is a civil suit against TVA on the equity side of the district court to recover "reasonable compensation for such infringement," that [**9] fact does not make the resulting suit any the less one for infringement of a patent. Thus, § 831r specifies the conditions that govern the patentee's suit for infringement, while § 1338(a) gives the district courts jurisdiction to hear that suit.

It would be anomalous if appeals in patent infringement suits against TVA were heard by the regional circuit, when all other appeals in patent infringement suits come to this court. (We have exclusive jurisdiction over appeals from the district courts in patent infringement suits generally, and over appeals from the Claims Court in suits for patent infringement against the United States, over which the Claims Court has exclusive jurisdiction under *28 U.S.C. § 1498*(a). *28 U.S.C. § 1295*(a)(1), (3).) Such a bifurcated jurisdiction would be inconsistent with the Congressional intent in enacting the Federal Courts Improvement Act of 1982 to "produce desirable uniformity in this area of the law." S. Rep. No. 275, 97th Cong., 2d Sess. 5 (1982), *reprinted in* 1982 U.S. Code Cong. & Ad. News 11, 15. There is no reason to believe that Congress intended the regional circuits rather than this court [**10] to hear appeals in this narrow category of infringement cases.

The earlier decision of the district court in this case, dismissing the suit against Westinghouse, is not inconsistent with this conclusion. The ground of that decision was that under *16 U.S.C. § 831r,* the patentee had no cause of action against Westinghouse because its "exclusive remedy with regard to the inspections for TVA is the claim for reasonable compensation asserted against TVA in this cause under Section [831r]." *Alco Standard Corp. v. TVA, 448 F. Supp. 1175, 1181, 197 U.S.P.Q. (BNA) 671, 675 (W. D. Tenn. 1978).*

The earlier decision did not hold that the jurisdiction of the district court in this case was based upon any statute other than *28 U.S.C. § 1338*(a). The district court began both that opinion and its later opinion on the merits by describing this suit as "a patent infringement action" and an "action for patent infringement," respectively. Although the district court's characterization of the case does not bind us, we see no reason to reject it. In sum, the district court action in this case arose under an [*1495] "Act of Congress [**11] relating to patents," and we therefore have jurisdiction over the appeal.

III

Validity of the '006 Patent

In challenging the district court's determination that the *'006* patent is valid, the appellants mount a broad scale but largely unfocused attack upon the sufficiency of the evidence to support the district court's factual

findings upon which its conclusion of validity rests. In effect, the appellants invite us to decide the case *de novo*. That is not our function, however; [HN2] our role is to determine whether the district court committed any reversible errors, either in its factual findings or in its legal conclusions or rulings. *Raytheon Co. v. Roper Corp., 724 F.2d 951, 956, 220 U.S.P.Q. (BNA) 592, 596 (Fed. Cir. 1983), cert. denied, 469 U.S. 835, 105 S. Ct. 127, 83 L. Ed. 2d 69 (1984).* The scattered and disorganized nature of the appellants' presentation has made the performance of our reviewing role more difficult.

In this appeal we do not specifically deal with the myriad of minor contentions that the appellants make, although we have [**12] considered them. Here we address only the major issues the parties have presented.

A. *The Enabling and Description Requirements (35 U.S.C. § 112 (1982)).*

The first two paragraphs of [HN3] *35 U.S.C. § 112* provide:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The district court ruled that the *'006* patent met the requirements of section 112. The court found that "one skilled in the art of ultrasonic testing could have determined how to make and use the patented invention from reading the patent specification, [**13] " that "the specification does adequately describe the claimed invention" because "evidence established one skilled in the pertinent part would be aware of the various methods and various equipment that could be used to obtain and record the [ultrasonic] data generated by the invention's transducers," and that the specification of the *'006* patent "supported" the claim. The district court further ruled that "after weighing all the evidence, the Court finds defendants have not proved the patented device was not able to achieve the results claimed in the patent."

On appeal, the contentions of both parties center around the language of the claims that pertains to correlating and combining the information derived from the ultrasonic scans. Claim 1 covers a "non-destructive test apparatus for detecting and providing three-dimensional analysis of flaws in a horizontally positioned generally cylindrical rotor" comprising, among other elements,

> position determining means providing for the direct correlation of the information content of a transmitted or reflected ultrasonic signal in one mode with the information content of reflected ultrasonic signals and unreflected transmitted [**14] ultrasonic signals in another mode,

and

> recording means for preserving the information content of said transmitted and said reflected ultrasonic signals in a fashion that permits combining the individual information content of each of said transmitted and said reflected ultrasonic signals in the different modes to derive an accurate indication of the existence, position, nature[,] size and shape of flaws in the rotor material.

The prosecution history of the *'006* patent demonstrates that the words "correlating" and "combining" have specific and [*1496] definite meanings, which one skilled in the art of the invention would have understood.

The word "correlate" as used in the *'006* patent refers to the steps of (1) taking the raw data from the ultrasonic scans in the various modes, (2) calculating the position of the defects -- circumferentially, longitudinally, and axially -- by using the angle of the probe, its depth into the rotor and the time it took for the ultrasonic pulse to be reflected back off the defects (flight time), and (3) grouping those calculated positions with others in the same general area. This grouping is necessary because [**15] a single defect may generate more than one ultrasonic blip (reflected ultrasonic pulse) during an entire test run due to the spread of ultrasonic beams and the use of multiple transducers. In the *'006* patent, to correlate means to group together all the ultrasonic blips that correspond to the same defect.

The word "combine" as used in the *'006* patent refers to gathering all the ultrasonic blips that have been correlated for one defect and using those blips to derive

information about the nature of the defect that any single blip might not have revealed. The inventor, speaking through his attorney, described "combining" best in an amendment filed with the Patent Office on October 19, 1975:

> Suppose that a pair of parallel cracks existed at the same angle with respect to the axis of the rotor as that followed by the shear waves, with the ends of these cracks overlapping but spaced apart. Testing with a straight [longitudinal] beam would show the presence of the two cracks, but would be unable to determine if the cracks were connected. On the other hand, testing with a shear wave would provide no signal at all. Therefore, this lack of any indication by the shear wave test [**16] would provide no information at all without combining the results of this test with the results of the longitudinal mode test, such combination revealing the existence of two separate cracks rather than a single connected crack.

The district court's holding that one skilled in the art would have known how to correlate and combine the ultrasonic scan data from a reading of the patent disclosure is not erroneous. *Raytheon, 724 F.2d at 960, 220 USPQ at 599.*

The appellants also contend that the correlating and combining steps of the *'006* patent are merely mental processes, and therefore, unpatentable. Under the meaning of correlating and combining used in the patent, these steps may be performed either by a person or by a machine. The record shows that the scan data are arranged and grouped using simple trigonometric calculations and graphic techniques. Any mental processes occur after the data has been subjected to calculation and graphing.

[HN4] The inclusion in a patent of a process that may be performed by a person, but that also is capable of being performed by [**17] a machine, is not fatal to patentability. *Diamond v. Diehr, 450 U.S. 175, 67 L. Ed. 2d 155, 101 S. Ct. 1048 (1981).* The presence of the steps of correlating and combining, which a machine is capable of doing, does not invalidate the *'006* patent.

B. *Anticipation (35 U.S.C. § 102(a) (1982)).*

[HN5] Under *35 U.S.C. § 102*(a), a patent is invalid if "the invention was . . . described in a printed publication in this . . . country . . ., before the invention thereof by the applicant for patent." We have held that "anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W. L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1554, 220 U.S.P.Q. (BNA) 303, 313 (Fed. Cir. 1983).* This is essentially the same standard the district court applied when it cited *American Seating Co. v. National Seating Co., 586 F.2d 611, 618, 199 U.S.P.Q. (BNA) 257, 261 (6th Cir. 1978), cert. denied, 441 U.S. 907, 99 S. Ct. 1999, 60 L. Ed. 2d 377, 202 U.S.P.Q. (BNA) 320 (1979),* [**18] which stated that "all the elements of a patented device . . . be found in a single pre-existing structure or description" (citations omitted).

[*1497] The appellants contended in the district court, and repeat the contention here, that a publication entitled "Ultrasonic Inspection of the Nimrod Power Plant" (Nimrod), which described a method and device for boresonically inspecting a rotor, anticipated the *'006* device patent. The district court held that the Nimrod publication did not anticipate the *'006* patent because there were three elements in the *'006* patent that were not disclosed in the Nimrod article:

1. "the Nimrod device does not teach simultaneous scanning with multiple transducers . . .";

2. "the Nimrod article . . . does not teach combining or correlating the information content of ultrasonic signals from the various modes"; and

3. "the Nimrod device . . . does not rotate around the internal circumference of the bore . . . ."

The district court did not specify which claims of the *'006* patent include the three elements that it found were not disclosed in the Nimrod article or whether each of the six disputed claims before us contains those three elements. [**19] In order to determine the correctness of the district court's findings of non-anticipation, therefore, a detailed comparison of the claims with the Nimrod article is necessary. The appellants have conceded that the Nimrod article does not anticipate claims 1, 2, and 3 of the *'006* patent:

> The *Nimrod* article is *anticipatory* of method claims 7, 8 and 10. *Nimrod* differs from apparatus claims 1-3 in that only a single mode transducer at a time was placed upon the Nimrod probe so that "simultaneous transmission of signals in various modes is not disclosed.

An examination of these claims, therefore, is not necessary. A comparison with the method claims, though, shows that each claim has at least one element not disclosed in the Nimrod article.

Claim 7 is directed at ultrasonic inspection. It includes the step of "combining the information [from the ultrasonic signals] to derive an accurate indication of the position, nature, size and shape of the flaws in the rotor material." Although the Nimrod article discloses three means for recording the output of the ultrasonic detector (Mk. VI flaw detector display unit, two channel flaw alarm unit, and an auxiliary [**20] display unit for "photographic recording purposes"), these recording means do not permit the combining of information.

Claim 8 describes in more detail the method described in claim 7. It includes the combining element of claim 7 not shown in the Nimrod article.

Claim 10, which depends upon claim 8, similarly contains the combining element of claim 7 that makes the Nimrod article not anticipatory.

In sum, claims 7, 8, and 10 are not anticipated by the Nimrod article. The district court's finding to that effect is not clearly erroneous. *Carman Industries, Inc. v. Wahl, 724 F.2d 932, 220 U.S.P.Q. (BNA) 481 (Fed. Cir. 1983).*

C. *Obviousness (35 U.S.C. § 103).*

1. The district court recognized the statutory presumption that a patent is valid *(35 U.S.C. § 282* (1982)). It ruled that the presumption of validity is weakened if there is prior art that is more pertinent than the art called to the attention of the Patent Office. It then concluded, however, that the "defendants did not present any evidence demonstrating why the art not cited to the patent office was more relevant or more pertinent than the art cited [**21] to the patent examiner, and the Court has found no ground for such a conclusion," and that the presumption of validity had not been weakened.

We have repeatedly held that [HN6] the existence of such uncited prior art does not weaken the presumption but merely makes it easier for the party challenging the validity of the patent to carry his burden of proof. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 U.S.P.Q. (BNA) 481 (Fed. Cir. 1984); Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 221 U.S.P.Q. (BNA) 669* (Fed. Cir.), *cert. denied, 469 U.S. 857, 105* [*1498] *S. Ct. 187, 83 L. Ed. 2d 120 (1984); Lear-Siegler, Inc. v. Aeroquip Corp., 733 F.2d 881, 221 U.S.P.Q. (BNA) 1025 (Fed. Cir. 1984).* The court's error in dealing with the effect of prior uncited art upon the presumption was harmless, however, in view of the court's holding that there was no prior art more pertinent than that called to the attention of the Patent Office. *Cf. Stratoflex Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534, 218 U.S.P.Q. (BNA) 871, 876 (Fed. Cir. 1983).* [**22]

The district court also erred in ruling that the presumption of validity could be overcome by a preponderance of the evidence. [HN7] The presumption may be rebutted only by clear and convincing evidence. *Jones v. Hardy, 727 F.2d 1524, 220 U.S.P.Q. (BNA) 1021 (Fed. Cir. 1984).* This error also was harmless, however, since the district court found that the appellants had not met the less exacting burden of proof the district court applied.

Portions of the district court's opinion do not focus upon the language of the claims of the *'006* patent -- both in comparing that patent with the prior art in determining obviousness and later in comparing it with the Westinghouse device in determining infringement -- but more broadly refer to the "patent" itself. Other portions of the opinion, however, indicate that the district court's comparisons were based upon the language of the claims. Our review of the record satisfies us that the district court's conclusion of nonobviousness was correct, and that its findings of infringement, discussed later, were not clearly erroneous.

2. In holding [**23] that the invention of the *'006* patent would not have been obvious to one of ordinary skill in the art at the time the invention was made, the district court applied [HN8] the criteria for determining obviousness announced in *Graham v. John Deere, 383 U.S. 1, 17-18, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966).* The court determined (i) the scope and content of [the] prior art," (ii) "differences between the *'006* claims and the prior art," and (iii) "the level of ordinary skill in the pertinent art." The court also discussed at length the "secondary considerations" relating to obviousness, including commercial success, long-felt but unsolved needs, and failure of others, an inquiry we have held is an essential and integral part of determining obviousness *vel non. Jones v. Hardy, 727 F.2d 1524, 220 U.S.P.Q. (BNA) 1021 (Fed. Cir. 1984); Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 220 U.S.P.Q. (BNA) 97 (Fed. Cir. 1984); Simmons Fastener Corp. v. Illinois Tool Works, Inc., 739 F.2d 1573, 222 U.S.P.Q. (BNA) 744 (Fed. Cir. 1981),* [**24] *cert. denied, 471 U.S. 1065, 105 S. Ct. 2138, 85 L. Ed. 2d 496 (1985).*

In determining the ordinary level of skill in the art, the district court found that Gilbert Ronca, a Westinghouse employee, was one of such skill. The appellants accuse the district court of not having made an adequate level-of-skill determination. We cannot say, however, based upon what the district court stated and what the record shows about Mr. Ronca's qualifications and his background and experience in the industry, that the district court's finding that the ordinary level of skill in the art was that of Mr. Ronca was clearly erroneous and did not constitute an adequate level-of-skill determination.

In evaluating the scope and content of the prior art and the differences between that art and the claims of the *'006* patent, the district court erred in concluding that "none of the prior art not cited to the patent office teaches combining the information content of the various modes of reflected and unreflected signals, as does the *'006* patent." U.S. Patent No. *3,221,544* (Gunkel), not cited to the Patent Office, discloses an electrical method for combining data from multiple ultrasonic [**25] scans. Moreover, [HN9] the question is not simply whether the prior art "teaches" the particular element of the invention, but whether it would "suggest the desirability, and thus the obviousness, of making the combination." *See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. (BNA) 543, 551 (Fed. Cir. 1985); Lindemann Maschinenfabrik GMPH v. American Hoist & Derrick, 730 F.2d 1452, 1462, 221 U.S.P.Q. (BNA) 481, 488 (Fed. Cir. 1984).*

[*1499] The district court described the Gunkel patent as a device which "detect[s] and analyze[s] defects in tubular articles such as pipes. The device inspect[s] pipes from the outer diameter. Multiple transducers transmit[] ultrasonic signals as the pipe [is] rotated spirally past the patented device." Although this statement was correct, the district court failed to recognize that the Gunkel device could electrically combine signals from multiple transducers.

The Gunkel patent is directed to an ultrasonic inspection system containing a "novel means for analyzing defect signals to [**26] determine the character of the defect." The Gunkel patent describes two methods of utilizing ultrasonic signals: by "primary" discrimination, and by "secondary" or "combinational" discrimination. Primary discrimination involves using only a single transducer to perform the study, while secondary or combinational discrimination utilizes multiple transducers and analyzes the combined signals from these transducers. The Gunkel patent further explains that

> insofar as is known, the prior art systems for defect discrimination have been primary discrimination systems which recorded the signals from the various transducers independently and relied upon analysis by the operator to provide the secondary information. However, such systems rely heavily upon the accuracy and judgment of the operator and provide considerable opportunity for human error.
>
> These disadvantages of the prior art systems are overcome with the present invention and novel means are provided for performing the secondary discrimination electrically in a manner which is substantially instantaneous and which completely eliminates the possibility of human error.
>
> The advantages of the present invention are preferably [**27] attained by providing novel means for ultrasonic inspection comprising a plurality of transducers, means for performing a primary discrimination of the signals from each of the transducers and electrical means for comparing and analyzing the results from all of the transducers to perform a secondary discrimination.

Although, as indicated, the district court noted that the Gunkel device used "multiple transducers [that] transmit[] ultrasonic signals as the pipe [is] rotated spirally past the patented device," apparently the court failed to recognize that a necessary element of the Gunkel device was the comparison of the data it obtained from the multiple transducers. In this respect, the Gunkel device performed a similar function to the correlation and combination functions of the *'006* patent.

The district court also erred in distinguishing the *'006* patent from the prior art on the ground that, unlike the prior art, "the patented device transverse[d] [sic] the internal bore of the material being inspected both axially and circumferentially and accomplish[ed] the inspection from the internal diameter of the item being inspected." Claims 1, 2, 7, 8, and 10, [**28] however, do not require longitudinal or circumferential movement of the probe. Only claim 3 requires such movement, and the Nimrod article clearly shows an angular drive means and a longitudinal drive means which operate independently of each other.

One of the differences between the claims of the *'006* patent and the Nimrod device was that the former, but not the latter, used multiple transducers. The district court found, however, and the finding is not challenged on appeal, that it was well known in the industry since 1960 that multiple transducers could be used simultaneously to scan an object. Additionally, the Gunkel patent indicates the utility of correlating and combining information from multiple modes, since it points out the disadvantages of using a single ultrasonic mode and the advantages of using multiple ultrasonic modes in a "secondary discrimination" system. Thus, standing alone, the prior art provides significant support for the appellants' contention that the *'006* patent would have been obvious.

3. [HN10] Prior art, however, cannot be evaluated in isolation, but must be [**29] considered [*1500] in the light of the secondary considerations bearing on obviousness. As we have pointed out:

> Evidence of secondary considerations may often be the most probative and cogent evidence of record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.

Stratoflex, 713 F.2d at 1538-39, 218 USPQ at 879; see also In re Piasecki, 745 F.2d 1468, 223 U.S.P.Q. (BNA) 785 (Fed. Cir. 1984).

In its lengthy discussion of secondary considerations, the district court found (a) that "the evidence is overwhelming that for well over a decade the industry had searched for a reliable method of detecting discontinuities in rotor forgings," (b) that "major turbine manufacturers had tried and failed to develop a reliable method of inspecting in-service turbine rotors," and (c) that "the patented device enjoyed commercial success and was perceived by Westinghouse and others as direct competition to Westinghouse's system of boresonic inspection." The appellants [**30] have not shown that those findings are clearly erroneous.

a. In 1963, ten years prior to the filing of the *'006* patent application, Westinghouse engineers were seeking a method of rotor inspection through the bore. A letter from one Westinghouse engineer to another said that "search units to examine rotors from the bore surface are and have been a need for many years" and that "there have been many times in the past when we could effectively use such units." At the time this letter was written, Westinghouse was using one of General Electric's boresonic test devices. Based on the letter, and testimony of Mr. Ronca and Mr. Renner of Westinghouse, the district court found that Westinghouse was not satisfied that the General Electric device was reliable.

The district court found that almost ten years later, in 1973, TVA asked Westinghouse to examine the possibility of performing rotor bore inspections. The district court based this finding on the testimony of Mr. Beck, a Westinghouse employee, that for a year following the Gallatin explosion, TVA insisted that Westinghouse obtain the capacity to perform rotor bore inspections.

b. The record shows that Westinghouse had attempted [**31] to discover a method of inspecting rotors from the bore, but had failed to find one that worked. Westinghouse department heads compared the device its own research and development efforts had produced, with Commercial's then existing device. Mr. Ronca's summary of the meeting states that some people present "expressed assessorial opinions regarding the technical superiority of the [Commercial] system. No attendee took exception to these assessments so acceptance of the [Commercial] system on a technical basis was considered unanimous." Later, Westinghouse had Commercial perform approximately 20 inspections for it using the device the *'006* patent covered, until Westinghouse had perfected its own system.

The evidence fully supports the district court's finding that others in the industry were unable to solve the problem. Westinghouse, a large corporation working on this matter, had tried but failed. Indeed, Westinghouse had pursued other solutions to the problem, using such technology as variable angle transducers, acoustical holography, and emersion testing. In 1972, when Commercial explained to Westinghouse officials its concept of a boresonic test apparatus, Mr. Ronca of Westinghouse [**32] stated that he thought the idea was not feasible because Westinghouse's own research endeavors to create such a device had failed. When shown in 1974 the Commercial device that the *'006* patent covered, Mr. Ronca expressed doubt that Commercial could have produced it. Yet two days later, Mr. Ronca wrote to Westinghouse department heads that "the [Commercial] system represents a significant advancement in the field of boresonics . . . ."

[*1501] c. The district court found, and the record shows, that Commercial had performed close to 100 inspections using the patented *'006* device, and that about twenty of those inspections had been performed for Westinghouse. The district court also cited a letter from Westinghouse to its field representatives urging them to discourage buyers from using Commercial's system and to push Westinghouse's system, from which the court inferred that Commercial was in active competition with Westinghouse in this technology. The court also cited a letter from an engineer at Detroit Edison stating that "[Commercial] is the forerunner and developer of on-site bore sonic [sic] and bottle bore equipment and are nationally recognized by EPRI [Electric [**33] Power Research Institute][,] Westinghouse, [General Electric] and others."

In this field of endeavor, where the number of bore inspections necessarily is relatively small, this is strong evidence of commercial success.

Westinghouse contends that these secondary considerations are irrelevant because Commercial's device did not operate effectively. Westinghouse cites the testimony of Dr. Gelhaus of EPRI describing Research Project RP502. In this project, Westinghouse and Commercial boresonic inspection devices were used to inspect a rotor that subsequently was cut apart and examined for defects. Dr. Gelhaus testified that the "techniques and the results were sorely wanting," and indicated that both test procedures produced inadequate results.

Batell Laboratories, one of the laboratories involved as an observer in the RP502 report, in reporting to the Consolidated Edison Company of New York on the analysis of stress and structural integrity it made of a generator rotor, stated that "the ultrasonic inspection of the rotor is by necessity performed from the bore surface only. Hence, flaw orientation is inherently difficult to determine. The system used by Commercial Machine Works [**34] represents the best solution available to this problem. Nevertheless, there is still a degree of uncertainty." Although Commercial's *'006* patented device might not have met Dr. Gelhaus' expectations, the industry apparently viewed the device as the best solution to the problem of boresonic inspection.

In light of the district court's findings and the evidence in the record, including the strong secondary considerations indicating nonobviousness, which weigh heavily in the determination of obviousness, *In re Piasecki, supra,* we agree with the district court's conclusion that the invention the *'006* patent covers would not have been obvious to one of ordinary skill in the art. This is one of those cases where evidence of secondary considerations "may . . . establish that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, 713 F.2d at 1538.*

IV

A. In finding that the Westinghouse device infringed the *'006* patent, the district court stated that Alco had presented "highly credible evidence, from two separate Westinghouse sources, that describe[d] Westinghouse's device for and method of boresonically inspecting [**35] turbine rotors," and that "neither defendant introduced evidence to discredit or rebut plaintiff's proof that the method and apparatus described in [the two sources] were the same method and apparatus used by Westinghouse to ultrasonically inspect TVA's rotors." The two Westinghouse sources were a Westinghouse Manual (called the "Blue Book") and a letter from Westinghouse's Steam Turbine Division Service Sales to one of its sales representatives that described the Westinghouse boresonic inspection system. The district court also noted that in an interrogatory Westinghouse had stated that it had used a boresonic system similar to the system described in the Blue Book to perform the TVA inspections.

The district court rejected the contention that Westinghouse's use of a gating procedure [*1502] avoided infringement. The court stated that gating is a means of masking unwanted data from the recorder so that only the relevant portion of the collected data is displayed. The court found that Westinghouse inspected rotors using two separate scans in which one scan performed a shallow analysis by gating out the inner wall of the rotor and the portion of the rotor beyond about eight [**36] inches, and in which the other scan performed a deep analysis by gating out the inner wall, the outer wall, and that portion of the rotor within about eight inches from the probe. The district court found that the *'006* patent did not require the inspection to be made on a single pass and that the Westinghouse method examined the entire rotor.

Finally, the district court rejected the contention that Westinghouse's device did not correlate or combine its data. Based upon its examination of the evidence, the court found that the Westinghouse device correlated and combined the information from its boresonic inspection.

The court stated that, "based on the evidence presented, the Court finds plaintiff . . . has met its burden of proving infringement . . . [and that] . . . the accused Westinghouse device contains every element found in claims 1, 2, 3, 7, 8 and 10 of the *006* patent."

B. In their appeal the appellants challenge, on various grounds, the finding that the Westinghouse device correlates or combines the data it obtains from the boresonic inspection of the rotor. As in the case of the appellants' challenge to the factual determinations underlying the conclusion of nonobviousness, [**37] our review of the record satisfies us that the findings relating to infringement are not clearly erroneous and were based upon correct legal standards.

1. The appellants first contend that there is no evidence that Westinghouse correlates or combines transmitted data using unreflected signals, as the *'006* patent requires. This argument rests upon a misconstruction of the patent claims. All of the claims specifically state that the correlation of the "information content" of the reflected and unreflected (transmitted) signals is accomplished "by precisely locating in a three-dimensional matrix the path through the rotor mass of each transmitted ultrasonic signal and the position of discontinuities in the rotor material evidenced by each reflected ultrasonic signal . . . ." If there is no reflected signal, the information content is that there is no indication of a flaw when viewed from that ultrasonic mode at that angle. The district court correctly

interpreted the claim language and applied it to Westinghouse's device.

2. The appellants next contend that the Westinghouse device uses a two-mode inspection only in the area from 3 to 8 inches from the bore and therefore does not [**38] operate "throughout the mass of the rotor material" as the patent claims require. Again, the appellants misread the claims.

The phrase in the claims, "the information content of said transmitted and said reflected signals relating to discontinuity characteristics throughout the mass of the rotor material," is a dependent clause which explains the meaning of the term "information content" used earlier in the claim. It requires not that the entire rotor be inspected with two modes, but only that the entire rotor must be inspected and the data correlated. Had the Westinghouse device inspected only a volume from three to eight inches from the bore with two ultrasonic modes, it would have avoided literal infringement. The Blue Book, however, states that "echos from about just beneath the bore surface to just beneath the exterior surface are recorded." Westinghouse searches the entire mass of the rotor and, therefore, literally employs this element of the *'006* patent.

3. The appellants argue that the Blue Book and the interrogatory answer do not prove that the Westinghouse device correlates and combines its data. This argument, however, ignores the third item of evidence upon which [**39] the district court relied, the letter from Westinghouse to one of its sales representatives. That letter describes the correlating and combining aspects of the Westinghouse device in terms [*1503] almost identical to the claim language: "a plot can be made which gives a spacial [sic] representation of the [defect's] size, shape, orientation and location."

4. Finally, the appellants contend that the district court inferred the existence in the Westinghouse device of an apparatus or means to correlate and combine data. With respect to the correlating feature, the Blue Book states that "the amplitude and length of time required for an echo to return is recorded, along with the longitudinal position and the rotational orientation. . . . Thus, the recorded echo time, longitudinal position and rotational position permit an accurate location of any discontinuity." Elsewhere the Blue Book states that

> each scan group is made with three ultrasonic transducers scanning simultaneously. Each transducer has a different orientation relative to the rotor interior. This not only permits a cross check of any ultrasonic findings by a single transducer but also permits the analyst [**40] to more precisely determine the location and orientation of any cracks or flaws that exist within the rotor interior.

As the district court found, since the Westinghouse device correlates the data, it must also have a means for doing so.

With respect to the combining aspect of the Westinghouse device, we have already noted the language in the letter from Westinghouse to one of its sales representatives which, as the district court said, "is an echo of the *006* patent's claims."

5. [HN11] Although the evidence of infringement is circumstantial, that does not make it any less credible or persuasive. *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 U.S.P.Q. (BNA) 805 (Fed. Cir. 1986).* In view of the nature of the device and the function it performed, it is not surprising that Alco was unable to produce direct evidence of infringement. Alco hardly could have been expected to present eyewitnesses to the use and operation of the Westinghouse device who would compare the Westinghouse device to the *'006* patent claims. The evidence Alco produced, however, is [**41] adequate to support the district court's finding that the Westinghouse device infringed the claims of the *'006* patent.

CONCLUSION

The judgment of the district court that the claims of the *'006* patent are valid and enforceable and that Westinghouse infringed those claims is affirmed.

AFFIRMED.

CONCURBY:

NIES

CONCUR:

NIES, Circuit Judge, concurring.

I concur in affirming the judgment of the trial court. In my view, appellants have failed to carry the burden of showing reversible error.

On the issue of infringement, appellants argue that the district court erred in holding that the Westinghouse "device" possesses a *means* to correlate and combine. Alco correctly asserts that claims 1, 2, and 3 require no such means. Those claims cover a device which produces data which is capable of being correlated and combined. Westinghouse's equipment also produces such data.

Thus, the district court's holding -- which was made, in any event, only with respect to claim 3 -- is harmless error. With respect to claims 7, 8, and 10, the method claims, those claims do include a step of correlating and combining the data. Westinghouse conceded that it does on occasion *itself* correlate or [**42] combine information, not merely furnish the data to others. Thus, that limitation in the method claims is met. I agree with Judge Friedman's infringement analysis in other respects and agree that all claims were proved to be infringed.

I also concur with Judge Friedman that the district court's conclusion that the claims are not invalid under section 103 cannot be disturbed. I believe, however, Judge Friedman misreads the district court's differentiation of the subject claims over the prior art Gunkel patent. Precisely, the district court spoke of no prior art teaching the correlation of *reflected* and *unreflected* signals. That Gunkel combined signals from multiple transducers [*1504] does not contradict the district court. Thus, I do not agree that the district court "failed to recognize" that Gunkel taught combining signals. Gunkel is irrelevant to the point the court was making. Indeed, I believe much labor is expended unnecessarily to uphold the patent on the record before us. Given the unique problems of on-site inspection of huge turbine rotors, Westinghouse's argument that the claims would have been obvious from the teachings of various prior art references appears [**43] to me to be a classic case of hindsight selection. Moreover, the reaction of Westinghouse personnel to the demonstration of Alco's device is persuasive as indicia of nonobviousness.

The dissent rejects the evidence of commercial success on the ground that the success must be attributed to Alco's services, not to the invention. The dissent considers that the examiner erroneously allowed amendments to the claims with respect to combining and correlating data which have no support in the specification. I disagree. Although raised below, there is no section 112 issue on appeal directed to the adequacy of the disclosure to support the claim language with respect to correlating and combining data. Such an assertion of error would be meritless. A fair reading of the specification supports the language of the claims, including the specific step in the method. The whole purpose of the acquisition of the data is to put the data together in a meaningful way so that the location and nature of flaws can be determined. The actual techniques for correlation and combining data are admitted by the parties to be well known in the prior art and are, thus, not required to be described in the specification. [**44] Thus, I depart from the dissent's analysis of this issue as a predicate for the denigration of the evidence of commercial success.

One final point, the panel has considered the question of this court's jurisdiction over the appeal, which depends upon the jurisdiction of the district court being based on *28 U.S.C. § 1338*(a). That section, in turn, requires that the claim arise under "an Act of Congress relating to patents." This suit is based on *16 U.S.C. § 831r* which is part of an Act "to improve the navigability and to provide for the flood control of the Tennessee River" and similar purposes. Judges Friedman and Rich conclude that the claim arises under an Act relating to patents; I do not. In my view a *16 U.S.C. § 831r* claim against TVA is more comparable to a claim under *28 U.S.C. § 1498* (1982) for reasonable compensation for use of a patented invention by the government, which does not arise under a patent statute, *Motorola, Inc. v. United States, 729 F.2d 765, 768, 221 U.S.P.Q. (BNA) 297, 299 (Fed. Cir. 1984),* and cases cited therein, than to a claim for patent [**45] infringement under *35 U.S.C. § 271.* The only decision directly bearing on this question was rendered in this very case by Judge Brown (reported at *448 F. Supp. 1175 (1978)).* In dismissing a claim against Westinghouse, Judge Brown held that Westinghouse could not be an infringer in view of the right of TVA to use the patented invention. Thus, this is a suit for compensation for a *lawful* use, not a suit for *unlawful,* i.e., infringing, use. That the word "infringed" as well as "used" appears in *16 U.S.C. § 831r* does not mean that Alco's claim is necessarily for patent infringement or arises under an act relating to patents.

DISSENTBY:

RICH

DISSENT:

RICH, Circuit Judge, dissenting.

The decision below is reported at *597 F. Supp. 133, 224 U.S.P.Q. (BNA) 577 (1984).* Reference will be made to the opinion as there published.

I am constrained to dissent from the majority's holding that the six claims in suit are not invalid for obviousness in view of the prior art under *35 USC 103.*

The majority opinion, after obviously careful consideration of the facts, preliminarily arrives at the conclusion [**46] that the claims in suit define only obvious subject matter and then reverses that conclusion because of the "secondary considerations," which I shall discuss further, concluding that

> [*1505] This is one of those cases where the evidence of secondary considerations "may . . . establish that an invention

> appearing to have been obvious in light of the prior art is not." *Stratoflex, 713 F.2d at 1538 [218 USPQ 871, 879 (Fed. Cir. 1983)].*

This is my point of disagreement. This is *not* one of these cases because, also per *Stratoflex*, a nexus is required between the invention disclosed in plaintiff's *patent* and the secondary considerations. No such nexus exists here.

The majority, like the trial judge, has been led astray and has assumed that the patent in suit is on some imaginary "system" for detecting flaws, which has enjoyed commercial success in the hands of Alco and was copied by Westinghouse, thus changing the prima facie obvious invention into a patentable invention.

What has happened here is that by a kind of magician's distracting patter, the purpose of which is to keep the viewer from observing what is actually happening, [**47] attention has been directed to the patent's claims to the exclusion of its *disclosure*. As the prosecution history shows, by a series of amendments the claims acquired a kind of life of their own, *divorced from the disclosure* of the patent's specification, including reference to what the majority opinion identifies as the "center" around which the contentions of the parties on appeal now revolve, namely, "the language of the claims that pertains to *combining* and *correlating* the information derived from the ultrasonic scans." (My emphasis.)

The sole function of claims is to delineate the *scope of protection* afforded by the patent, not to *describe* what the patentee has invented. Claim language, by law, is supposed to find support in the specification. Unsupported claim limitations should be ignored in appraising commercial success, though it could be a ground for invalidating the claim, but I am not discussing that issue. In determining what was invented, the specification must be considered in the state in which it was filed and the *original* claims, which are a part of it, may be regarded as a part of that disclosure. The patent and its file history, which [**48] are legal documents, are before us and it is necessary to consider them to determine what the invention disclosed therein truly is. In fact, that should be the first order of business. The salient fact that emerges from such examination is that *there is no reference whatsoever in the specification and original claims, taken together, of combining or correlating anything*, or of any means for or method of performing the function of combining or correlating. These are simply *terms* injected into the claims by the prosecuting attorney, without any support in the disclosure, in an effort to persuade the examiner that the claims patentably *distinguished* from the prior art he had cited against them. It does not appear to me that the examiner ever compared the claims he allowed with the disclosure to see if they are supported by it.

When the majority opinion refers to "the meaning of combining and correlating used in the patent" (in Part III, A) it must be borne in mind that those terms are not "used in the patent" insofar as the *disclosure* thereof is concerned, but merely appeared in the claims long after the application was filed. It must also be borne in mind that the majority [**49] has correctly held that "one skilled in the art would have known [before Smith's invention] how to combine and correlate the ultrasonic scan data" -- a finding also made by the trial court -- for which reason it is part of the prior art and therefore *can be no part of what Smith invented.* It was a skill of the art and a difficult one at that, comparable to the skill required of a radiologist in interpreting X-rays or CAT scans in deducing the existence of tumors.

Prima Facie Obviousness

The majority finds significant error by the district court in the following respects:

1. In failing to realize that the Gunkel patent reference, not considered by the PTO, discloses electrically *combining* ultrasonic [*1506] signals from multiple transducers, in a flaw detection system, to compare and analyze the results, and thus "performed a similar function to the combination and correlation functions of the *'006* patent [claims]." (Of course, as I have just pointed out, the *'006* patent in suit *does not disclose* any such functions.)

2. In not understanding that the "Nimrod" article reference (Brooks et al. "Ultrasonic Inspection of the Nimrod Power Plant Alternator [**50] Rotors") discloses both longitudinal and angular drive means for the ultrasonic inspection of rotor bores. Those are the very same functions Smith's apparatus was designed to perform, in which, therefore, there is no novelty.

The majority also notes that the district court correctly found that it had been *well known in the industry since 1960* that multiple transducers could be used simultaneously to scan an object and that this finding is not challenged on appeal.

On the basis of the foregoing, the majority holds that "the prior art provides significant support for appellants' contention that the *'006 patent* would have been obvious," (my emphasis) by which, I presume, the majority means that the *inventions* (apparatus and method) of the claims in suit would have been obvious. This is what I refer to as its holding of prima facie obviousness, with which I wholeheartedly agree. As a preliminary to discussing why the majority should not back away from that holding, let me summarize in one

paragraph what the basis of that finding of prima facie obviousness is.

Long prior to Smith's supposed invention, the ultrasonic detection of flaws in metal parts was a highly developed [**51] and sophisticated art. Smith's filing date was Dec. 3, 1973. Over ten years before that, Gunkel taught the use of multiple transducers operating simultaneously, longitudinally of and around tubular articles such as pipe, but on the outside, to detect flaws with use of electrical analysis means *to combine and correlate* the data produced by the transducers and their related pickups, to detect and appraise the nature of flaws. Gunkel proposed using as many as four transducers generating as many different modes of signals to get as many different kinds of data. The Nimrod disclosure shows the use of ultrasonic testing conducted *from the inside of a bore* of a shaft, as in the *'006* patent, through which the transducers are moved longitudinally and angularly rotated. Necessarily, some indexing means for accurately determining where the transducers are at the time when any given signal is received must be, and was, employed in all such apparatus or it would not be known where the flaws are. So the patentee did not invent that function.

What the *'006* patent *discloses* as Smith's invention is simply a piece of mechanism for use in selectively positioning one or more transducers [**52] and pickups in a bore and simultaneously "indexing" to indicate or record the longitudinal and angular position, i.e., the exact location, of the transducers in the bore to show where they are when signals are received. *The totality of Smith's disclosure of what he does with any signals received* is contained in the underlined words in the following sentence, taken in conjunction with the single "schematic" (i.e., not a working) drawing in the patent, reproduced below:

> If the propagated [ultrasonic] waves contact a flaw, there is a reflection to the pick-up means at the appropriate source 45 or 47, and *an appropriate indication is sent back to a recording or display device 87.* [Col. 5, lines 65-68.]

[*1507] [SEE ILLUSTRATION IN ORIGINAL]

The "recording or display device 87" is not described further but merely indicated, as some alternative and *presumed known device of the prior art*, by the square at the lower left corner of the schematic figure containing the number 87. Furthermore, it will be seen in the drawing that box 87 is shown as connected to a line 13. Line 13 is described in the specification (col. 3, 11. 35-39) as an "air line" [**53] which carries pneumatic pressure into the device to actuate the legs 11 on supports 3 and 5, a function totally unrelated to recording or displaying signals. Signals presumably would be conducted by "electrical lines 77" (col. 5, 1. 34), not further described and not shown as connected to anything, since the signals are electrical. *In sum, the patent disclosure is wholly devoid of any means or method for the "correlation of the information content of a transmitted or reflected ultrasonic signal" or for "combining the individual content" of signals* (to quote *claim* language) *or of any teaching of how to accomplish either of those functions.* The claims in suit, therefore, were created out of the whole cloth by the imagination of the prosecuting attorney and based on knowledge of prior art or subsequent events, not on the teachings of the *'006* patent. One must be wary of such expressions, used in the majority opinion, as "the device the *'006* patent covered" and "the patented *'006* device." They fail to distinguish between the *invention* disclosed in the patent and other things which may fall within the scope of the later-filed claims.

The majority opinion, at slip op [**54] page 9, refers to "an amendment" as containing the *inventor's* best description of "combining." What is in fact referred to is *attorney argument*, in connection with an amendment, during prosecution and contained in "AMENDMENT 'B'" in the section headed "REMARKS" (Apx. 158, 166, 170). This is no part of the patent disclosure and cannot be relied on to supply deficiencies therein. Even if it had been an actual proposed amendment, it would not be part of the disclosure, any more than attorney argument in this court. Attention is further directed to the fact that "Amendment 'B'" was refused by the examiner and *never entered* (A-176) and was replaced by "Amendment 'C'" (A-195). In any event it is not the *inventor's* description.

It is also a significant fact that the inventor, Robert D. Smith, named in the patent issued to Alco, left the employ of Alco in [*1508] October 1973 before the application was filed on December 3, 1973. He testified on deposition that after it was filed he never had any knowledge of the prosecution or any contact with the attorneys (A-1518, 1541-42).

When we come to examine whether there was commercial success of Smith's *invention* we are, [**55] of course, concerned only with the success of what he both invented and disclosed. *If there was commercial success, that success does not count in appraising non-obviousness unless it can be attributed to what he both invented and disclosed.* In light of all of the foregoing, I am convinced, as a matter of law, that unless there is a clear *nexus* between the *disclosed* subject matter of the patent (not just the vagueness of later-conceived broadly

worded claims) and very significant secondary considerations the claims are invalid for obviousness.

No Nexus

Without nexus, of course, the invention that is disclosed in the patent does not enjoy the benefits of commercial success in appraising its nonobviousness. The district court discusses nonobviousness beginning at *596 F. Supp. at 147, 224 USPQ at 586,* in part B of its opinion. Under sub-heading 3, "Ordinary skill in the art." The court several times refers to the invention of the patent as a boresonic inspection "system," or the "patented system." But *no system is disclosed* in the patent; the court must, therefore, have had in its mind something in addition to what the *'006* patent discloses. In section [**56] 4(c), "Commercial success," it gets to a brief discussion of that subject (F. Supp. at 153, USPQ at 591). One will search in vain for any description of just *what* it was that enjoyed commercial success. The record makes clear, however, that the Commercial Machine Works (CMW) division of Alco, which is supposed to have had the commercial success, was operating a *service business* of testing turbine rotors in the field, moving to the site with its equipment and personnel. One such test may take as long as a week or ten days, hundreds or even thousands of readings being taken (A-1016). When it is over, the net result is a report (A-1470) from CMW to the owner of the rotor saying what it thinks of the soundness of the rotor, what if any probable flaws or "discontinuities" have been found, and a record of its tests, columns of numbers representing "A" scan data (A-1469), which can be used later for comparison with subsequent tests. Nobody will ever know whether the report is or is not accurate, or how accurate, unless the rotor is physically altered by machining (as by "bottle-boring") (A-1474) or cut to pieces as a check on the tests.

Now, the totality of the commercial success [**57] found by the district court was that Westinghouse, which is a manufacturer of turbines, as well as a field-testing competitor of CMW, employed CMW in a crisis situation to test some 20 rotors in the field because it thought CMW was, at the time, the most competent operator in the field, and that CMW may have made a total of "[close] to a hundred" such inspections altogether. The question is, what does this prove about commercial success of the invention disclosed in the Smith patent, which is a piece of apparatus for locating transducers and pick-ups in a rotor bore -- nothing more. Is that apparatus the principal reason CMW was hired to make tests? Hardly. CMW was hired because *it* was considered competent to make tests. The apparatus disclosed in the patent is but *part* of the equipment necessary to obtain "A" scan data; it does not produce that data by itself, it only positions the transducers. The transducer must be powered by frequency generators, not shown but known to the prior art. The frequency generators must produce different frequencies. Different transducers must be used to produce different "modes" of ultrasonic waves, also not explained in the patent but known [**58] to the art. When the transducers are energized and send back data through the pick-ups, that electrical data must be recorded by undisclosed instruments (except for box 87), also known to the prior art. And even after that is done, the thus-recorded [*1509] data must be interpreted by highly trained and skillful personnel in order to provide the information being sought. (Wallace A-1468 et seq.; Gelhaus A-1493 et seq.) Computers may be used which have to be properly programmed. And when all is said and done, there is no assurance that the deductions from the data are really true.

What it comes down to is that CMW's success in selling its testing services to rotor users depended on its customer's confidence in CMW's abilities as the best available testing service organization. Since the most important aspect of such confidence, as the majority has deduced from these adversary proceedings, was CMW's technical ability through its personnel to *correlate* and *combine* the information content of the ultrasonic signals (matters on which the patent gives no instructions whatsoever) to arrive, perhaps with the aid of a "fracture mechanic's analysis" (A-1472), at conclusions on [**59] the condition of the rotor tested. Therefore, it appears clearly to me that the only commercial success relied on here or below cannot be attributed to Smith's invention as disclosed in his patent but must have been due primarily to other factors. It follows that there has been no showing of nexus between Smith's prima facie obvious invention and the commercial success to take the invention out of the obviousness category.

I also emphasize that what has become the crux of this case as the supposed contribution of the patentee -- correlating and combining data obtained from ultrasonic tests -- has been thoroughly established by the record as a technical skill which existed in the *prior art* long before the patentee's invention. The mere presence of these correlating and combining limitations in the *claims* by reason of an attorney's effort to distinguish them from the disclosures of references is not a justification for treating them as part of Smith's invention as though they were his contribution to the art. True, they are a vital part of CMW's *services*, which have been successfully sold, but correlating and combining remains knowledge of the art free for all to practice. [**60] What is free to all cannot be attributed to the patentee.

I would therefore hold the claims in suit invalid for obviousness under § 103.

The issue of *nexus* is definitely before us on appeal. Appellants' main brief devotes 10 pages to arguing *lack of nexus*, 20% of appellants' entire argument. Nexus is of the utmost significance in reaching the correct result on the obviousness issue because, as I have said, it is the *only* basis used by Judge Friedman to escape from his preliminary conclusion that the prior art makes the claims in suit obvious, which conclusion is clearly right.

Appellee has chosen to *avoid* answering the arguments that nexus was not established by almost totally ignoring them. Literally, its brief contains only a single short sentence on the question. It reads (p. 36):

> It is hard to see how there was a lack of nexus when Westinghouse copied *the patented invention* and even arranged with CMW to conduct inspections for it on a subcontract basis by utilizing the apparatus and method *that it had patented*. [Emphasis mine.]

Now, it is "the patented invention" that I have been discussing and what I mean by it is the invention [**61] that Smith made and disclosed in his patent. What else could he have patented? I have tried to determine whether the so-called commercial success which led the lower court and Judge Friedman, and apparently Judge Nies also, to find commercial success and thus nonobviousness is properly *attributable* to what Smith disclosed as his invention so as possibly to tip the scales in favor of finding prima facie invalid claims valid. I am convinced it is not. CMW's business success is not shown to be success of the Smith invention.

Judge Nies is swayed in favor of nonobviousness by "the reaction of Westinghouse personnel to the demonstration of *Alco's device*." (My emphasis.) What device? The person from Westinghouse who was swayed was Gilbert E. Ronca. His [*1510] testimony is not voluminous (A-1070-1135) and it clearly shows what impressed him. It was definitely *not* the disclosure of Mr. Smith's patent. I will summarize what the record shows.

Mr. Ronca was sent by Westinghouse to CMW to look at their boresonic *system* (A 1106). There was nothing new about boresonic systems as such; General Electric had one and the Nimrod apparatus was another. Smith did not invent, and [**62] his patent does not disclose, a "system," yet that is what everyone involved in this case, including the trial court, persistently talks about. A system is, of course, what one has to have to do boresonic testing. Mr. Ronca saw a demonstration of the *CMW system*, not the invention, and he was given information about it by two employees of Southwest Research Institute, which had built the system for Alco (CMW). The Southwest people were longtime experts in ultrasonic testing, research, and equipment design. In fact they appear to have designed the device shown in Smith's patent. In fact, the schematic drawing of the patent appears to have been copied from a submission to CMW from Southwest. Mr. Ronca wrote a report and he testified about his impressions *of the CMW system*. He said, "The system is very flexible and is functionally modular. By using the building block concept, the number and the type of examinations can be suited to a pre-established examination program. . . . The equipment used had a.001 inch reset capability, both in the axial and circumferential directions." (A 1125) "As I tried to describe, the system was described as accepting preprogrammed P.C. [printed circuit] [**63] boards which offered a selection of scanning sequences such as scanning axially over a pre-selected length and indexing clockwise. . . . It had several different options. It also had options to accept different scan modes and different scan -- in a menu of scan programs, such as surface waves, any combination of shear waves and so forth. And these could be plugged into the system." (A 1127) Explaining the reference to "menu," Ronca said that there were also representations about the capability of "marrying" the CMW device to a mini-computer. Asked about that, he said "this was the reference I made on having a menu of protocols that could be inserted for scan purposes." (A 1130) On all of this, Mr. Ronca reported enthusiastically and recommended Westinghouse try to buy it.

One will search in the patent in suit in vain for any disclosure or teaching of the things that so impressed Mr. Ronca in the CMW *system* or for a disclosure of any system at all.

I reiterate that the only commercial success of the *CMW system* relied on below is that company's *testing* of a total of, perhaps, 100 rotors. That testing was necessarily done by using the system, not merely the device shown [**64] in the patent, which in itself cannot test anything. There is no showing that the tests were accurate and there is considerable evidence that they may not have been. *All we know is that CMW was hired to do them* because their customers considered them competent. To my mind, that is no proof that CMW's success in getting that much testing business was due to the invention disclosed in Smith's patent. All it can do is position transducers in a bore and tell you where they are. That had been done in the prior art. One always has to know where the transducers are or it is impossible to determine where the flaws, if any, are. The accuracy with which it does so depends entirely on the refinement of the machining by which the locator is manufactured. The Nimrod boresonic device was said to be just as accurate, if not more so. All the rest -- the interpretation of the signals to acquire some intelligence and the apparatus and instrumentation essential thereto -- was the *common*

knowledge of the ultrasonic nondestructive testing art, as my colleagues point out whenever I suggest non-disclosure of some claim limitation in the patent.

One should not be overly impressed by the background [**65] recitation of nonspecific, arcane, ultrasonic terminology about wave propagation modes, all of which was knowledge in the public domain. Aside from Smith's piece of machinery, which is generally [*1511] described without particularization on the basis of a mere schematic figure, Smith does not give a single example of how to practice any method. He merely recites a multitude of general possibilities. Neither does he explain how to achieve his much-touted thousandth of an inch location accuracy.

I hesitate to suggest that my learned colleagues have been gullible, but on the subject of "commercial success" it does seem to me that they have been unduly moved by mere words and innuendos. Just what was the supposedly successful *CMW system*? They do not say. I have seen no reference in the briefs to any clear evidence on the subject and have been unable to find it in the voluminous record.

It is asserted as another indicium of nonobviousness that Westinghouse "copied" *the CMW system* and used it to do testing for TVA. There is a picture of the transducer-carrying head used by Westinghouse at A 536.20 and at tab 7 of appellants' brief. It bears little resemblance to the schematic [**66] drawing of Smith's patent. Where, then, do we find the evidence of the commercial use *of the invention disclosed in the patent* in either the CMW system or Westinghouse's alleged infringing copy? Unless and until it has been shown that there has been commercial use of the piece of mechanism disclosed in Smith's patent (which is not a system) there has been no proof of commercial success of his invention and no evidence establishing the necessary *nexus*. Finding no nexus, I would hold the claims in suit obvious and invalid under *35 USC 103*.

Jurisdiction

I join Judge Friedman in finding that this court has jurisdiction and find no merit in Judge Nies's grounds for questioning it. Notwithstanding the location of § 831r in a title of the U.S. Code other than Title 35, the section is an Act of Congress relating to patents, as is *28 USC 1498* which is controlling on other suits against the government for the use of patented inventions. *Motorola, Inc. v. United States, 729 F.2d 765, 221 U.S.P.Q. (BNA) 297 (Fed. Cir. 1984)* says nothing to the contrary.

Having given consideration to *16 USC § 831r* [**67] for the first time in connection with this appeal, I am impelled to say that it is, from the standpoint of patent law, one of the most ineptly drafted statutes I have seen, displaying a confusion between patents and patented inventions, and a total lack of comprehension of what the patent right is. One cannot copy a patent right, which is only the right to exclude, or use it, or employ it, all of which § 831r mentions in meaningless confusion. Only the owner of a patent or an exclusive licensee with the right to sue, who is a virtual owner, can use or employ the right to exclude. In spite of these misfortunes, however, the intent is clear that when TVA uses a patented invention and thus infringes the patent, the exclusive remedy is a suit against TVA "on the equity side of the appropriate district court of the United States. . . ." Since this is an act relating to patents, jurisdiction of the district court is under *28 USC § 1338*(a) and we have jurisdiction under *28 USC § 1295*(a)(1).

LEXSEE

SCRIPPS CLINIC & RESEARCH FOUNDATION, REVLON, INC., and RORER GROUP INC., Plaintiffs-Appellants, v. GENENTECH, INC., Defendant/Cross-Appellant, and MILES, INC., Defendant-Appellee. SCRIPPS CLINIC & RESEARCH FOUNDATION and REVLON, INC., Plaintiffs-Appellants, v. CHIRON CORPORATION, Defendant-Appellee

Nos. 89-1541, 89-1542, 89-1543, 89-1646, 89-1647

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

927 F.2d 1565; 1991 U.S. App. LEXIS 3925; 18 U.S.P.Q.2D (BNA) 1001

March 11, 1991, Decided

SUBSEQUENT HISTORY:

As Corrected March 26, 1991. Rehearing Denied April 30, 1991, Reported at: *1991 U.S. App. LEXIS 8701.* Suggestion for Rehearing In Banc Declined May 14, 1991, Reported at: *1991 U.S. App. LEXIS 33486.*

PRIOR HISTORY: [**1] Appealed from: U.S. District Court for the Northern District of California; Judge Schwarzer.

DISPOSITION:

Affirmed In Part, Reversed In Part, Vacated In Part, And Remanded

CASE SUMMARY:

PROCEDURAL POSTURE: Consolidated appeals from the United States District Court for the Northern District of California, which issued four opinions concerning litigation about a patent for a complex protein essential to blood clotting and decided several motions for summary judgment. Each party challenged the adverse decisions against that party.

OVERVIEW: Plaintiffs, assignee and licensees of a patent for a complex protein naturally occurring in normal blood and essential to blood clotting, sued defendants for patent infringement. In four opinions, the district court decided several motions for summary judgment. By appeal and cross-appeal, each party challenged the adverse decisions against that party. The court held that the element of intent was essential to the defense of inequitable conduct, and remanded the dispute about the credibility of the inventors' statements about the purity of the product. Subjective intent was not determinative of the need for a reissue application, however, and so plaintiffs were entitled to summary judgment on that issue. Defendants' contention that the reverse doctrine of equivalents applied raised questions of scientific and evidentiary fact requiring a trial. The court also held that product-by-process claims were not limited to product prepared by the process set forth in the claims.

OUTCOME: The court decided the issues were appropriately decided summarily, including plaintiffs' need for a reissue application and compliance with the best mode requirement. The court reversed and remanded the issues on which summary judgment was inappropriately granted, including the defenses of inequitable conduct, enablement, and anticipation.

LexisNexis (TM) HEADNOTES - Core Concepts:

Civil Procedure > Summary Judgment > Summary Judgment Standard

[HN1] Summary judgment is a useful procedural tool whereby an unnecessary trial is avoided when there are no material facts in dispute. However, summary proceedings are not intended to substitute for trial when it is indeed necessary to find material facts. A factual question is material if a reasonable jury could return a

verdict for the non-moving party based at least in part on its determination of the factual question. In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the opponent of the motion, and doubts resolved in favor of the opponent.

Civil Procedure > Summary Judgment > Burdens of Production & Proof

[HN2] A motion for summary judgment must be supported with a sufficient showing to establish that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. The burden of establishing entitlement to summary disposition is with the movant, with due consideration to the burden of proof. When a sufficiently supported motion has been submitted, the burden of coming forward and showing that there is a genuine issue of material fact shifts to the non-movant. All that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial. However, if the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.

Patent Law > Specification & Claims > Enablement Requirement

[HN3] The enablement requirement set forth in *35 U.S.C.S. § 112,* para. 1, is that the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. The purpose of this provision is to assure that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and the knowledge in the art.

Patent Law > Specification & Claims > Enablement Requirement

[HN4] Open-ended claims are not inherently improper; as for all claims their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art. They may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit.

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect

[HN5] The materiality of a representation, and whether the representation was made with intent to deceive or mislead, are the two essential factual predicates to determination of inequitable conduct. The element of intent is essential as a matter of law to a ruling of inequitable conduct. Conduct that requires forfeiture of all patent rights must be deliberate, and proved by clear and convincing evidence.

Civil Procedure > Summary Judgment > Summary Judgment Standard

[HN6] The fact that both sides moved for summary judgment does not establish that there is no issue of fact and require that judgment be granted for one side or the other.

Civil Procedure > Summary Judgment > Summary Judgment Standard

[HN7] Where there is a question of law, and the facts material to that question are not in dispute, the matter may be decided summarily.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN8] The reissue statute, *35 U.S.C.S. § 251,* provides in part that whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application. No new matter shall be introduced into the application for reissue.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN9] The applicant for reissue must specify the errors relied upon, and how they arose or occurred, and must distinctly specify the excess or insufficiency in the claims; and the applicant must declare the absence of deceptive intention.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN10] Under *35 U.S.C.S. § 251,* broadened claims by reissue must be applied for within two years of grant of the original patent.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN11] An error of law is not excluded from the class of error subject to correction in accordance with the reissue statute. Although attorney error is not an open invitation

to reissue in every case in which it may appear, the purpose of the reissue statute is to avoid forfeiture of substantive rights due to error made without intent to deceive. The reissue statute is based on fundamental principles of equity and fairness. When the statutory requirements are met, reissuance of the patent is not discretionary with the Commissioner; it is mandatory.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN12] The law does not require that no competent attorney or alert inventor could have avoided the error sought to be corrected by reissue. Failure of the attorney to claim the invention sufficiently broadly is one of the most common sources of defects in patents. The fact that the error could have been discovered at the time of prosecution with a more thorough patentability search or with improved communication between the inventors and the attorney does not, by itself, preclude a patent owner from correcting defects through reissue.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN13] Subjective intent is not determinative of whether the applicants erred in claiming less than they had a right to claim. Intent to claim is not the criterion for reissue, and has been well described as but judicial shorthand, signifying a means of measuring whether the statutorily required error is present. The statutory standard of reissuable error is objective, and does not require proof of subjective state of mind. Determining what protection an inventor intended to secure by an original patent for the purposes of *35 U.S.C.S. § 251* is an essentially factual inquiry confined to the objective intent manifested by the original patent.

Civil Procedure > Summary Judgment > Summary Judgment StandardPatent Law > Novelty & Anticipation

[HN14] The patent law issue of anticipation is a question of fact. To make such finding on summary judgment, the court must determine that no facts material to the question are disputed; or that even if all material factual inferences are drawn in favor of the non-movant, there is no reasonable basis on which the non-movant can prevail. The standard of proof that would have to be met at trial must be considered.

Patent Law > Novelty & Anticipation

[HN15] Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.

Patent Law > Novelty & Anticipation

[HN16] The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference.

Patent Law > Infringement > Acts of Infringement

[HN17] In patent cases, questions by affidavit is disfavored. Trial by document is an inadequate substitute for trial with witnesses, who are subject to examination and cross-examination in the presence of the decision-maker.

Patent Law > Specification & Claims > Best Mode

[HN18] Title *35 U.S.C.S. § 112* provides in part that the specification shall set forth the best mode contemplated by the inventor of carrying out his invention.

Patent Law > Specification & Claims > Best Mode

[HN19] Compliance with the best mode requirement is a question of fact, and invalidity for failure of compliance requires proof by clear and convincing evidence that the inventor knew of and concealed a better mode of carrying out the invention than was set forth in the specification.

Patent Law > Infringement > Claim Interpretation

[HN20] Claim interpretation is a question of law, having factual underpinnings. When the meaning of key terms of claims is disputed extrinsic evidence may be adduced including testimony of witnesses, and reference may be had to the specification, the prosecution history, prior art, and other claims.

Patent Law > Infringement > Doctrine of EquivalentsPatent Law > Infringement > Reverse Doctrine of Equivalents

[HN21] The so-called "reverse doctrine of equivalents" is an equitable doctrine invoked in applying properly construed claims to an accused device. Just as the purpose of the "doctrine of equivalents" is to prevent pirating of the patentee's invention, so the purpose of the "reverse" doctrine is to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention.

Patent Law > Infringement > Reverse Doctrine of Equivalents

[HN22] The reverse doctrine of equivalents flows from the Supreme Court's statement in Graver Tank that an accused article may avoid infringement, even if it is within the literal words of the claim, if it is so far changed in principle from a patented article that it performs the same or a similar function in a substantially

different way. Application of the doctrine requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims, which in turn is determined in light of the specification, the prosecution history, and the prior art.

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect
[HN23] A reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct.

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect
[HN24] When a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it can not be deemed to have been withheld from the examiner.

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect
[HN25] A reference that is material only to withdrawn claims can not be the basis of a holding of inequitable conduct.

Patent Law > Inequitable Conduct > Burdens of Proof
[HN26] The party with the burden of proof of inequitable conduct must meet the clear and convincing standard.

Civil Procedure > Appeals > Reviewability > Preservation for Review
[HN27] In the Ninth Circuit, an appeal from a final judgment may include challenges to all rulings that produced the judgment.

Patent Law > Specification & Claims > Claim LanguagePatent Law > Infringement > Doctrine of Equivalents
[HN28] Product-by-process claims are not limited to the product prepared by the process set forth in the claims.

COUNSEL:

William S. Feiler, Morgan & Finnegan, of New York, New York, argued for Plaintiffs-Appellants. With him on the brief were Eugene Moroz, Patricia S. Rocha, Bruce A. Pokra and Stephen V. Bomse, Heller, Ehrman, White & McAuliffe, of San Francisco, California, of Counsel.

James W. Geriak, Lyon & Lyon, of Los Angeles, California, argued for Defendant/Cross-Appellant. With him on the brief were Douglas E. Olson, Bradford J. Duft and Karol M. Pessin. Also on the brief were Thomas J. Morgan and Melvin Blecher, Lyon & Lyon, of Washington, District of Columbia, Arnold Sprung, Sprung Horn Kramer & Woods, of New York, New York, argued for Defendant-Appellee. With him on the brief were Nathaniel D. Kramer and Alan J. Grant.

William L. Anthony, Townsend & Townsend, of Palo Alton, California, represented Chiron Corporation. Of Counsel was Noemi C. Espinosa, Townsend & Townsend, of Palo Alton, California.

JUDGES:

Markey * and Newman, Circuit Judges, and Beer, District Judge. **

* Circuit Judge Markey vacated the position of Chief Judge on June 27, 1990.

** The Honorable Peter Beer, United States District Court for the Eastern District of Louisiana, sitting by designation. [**2]

OPINIONBY:

NEWMAN

OPINION:

[*1568] NEWMAN, Circuit Judge.

This litigation concerns a substance called human Factor VIII:C, a complex protein that occurs naturally in normal blood and is essential to the clotting of blood. The patent in suit, United States Reissue Patent No. *32,011* (the "R *'011*" patent), is entitled "Ultrapurification of Factor VIII Using Monoclonal Antibodies", inventors Theodore S. Zimmerman and Carol A. Fulcher. Assigned to Scripps Clinic and Research Foundation, it was licensed exclusively to Revlon, Inc. Subsequent to the filing of this suit Revlon sold its interest to Rorer Group, Inc.

By appeal and cross-appeal, the parties n1 raise various issues of patent validity and enforceability, infringement and inducement to infringe, and reissue law and practice, all of which were decided on motions for summary judgment. Each side challenges the decision of certain issues adverse to it, and the final judgment based thereon. n2

n1 The plaintiffs will be grouped as "Scripps" unless otherwise stated. The defendants will be grouped as "Genentech" unless otherwise stated.

n2 These consolidated appeals and cross-appeals arise from judgments and orders of the United States District Court for the Northern District of California. *Scripps Clinic & Research Foundation v. Genentech, Inc., 666 F. Supp. 1379, 3 U.S.P.Q.2d (BNA) 1481 (N.D. Cal. 1987); Scripps Clinic and Research Foundation v. Genentech, Inc., 678 F. Supp. 1429, 6 U.S.P.Q.2d (BNA) 1018 (N.D. Cal. 1988)* (on reconsideration); *Scripps Clinic and Research Foundation v. Genentech, Inc., 707 F. Supp. 1547, 11 U.S.P.Q.2d (BNA) 1187 (N.D. Cal. 1989);* and *Scripps Clinic and Research Foundation v. Genentech, Inc., 724 F. Supp. 690, 12 U.S.P.Q.2d (BNA) 1157 (N.D. Cal. 1989)* (Order).

[**3]

The Invention

Factor VIII:C, called the clotting or procoagulant factor, is found in all mammals, although it differs among species. It has been the subject of extensive scientific research, over many years. At the time the claimed invention was made, it was known that human Factor VIII:C is a complex protein produced by the Factor VIII:C gene and secreted into the blood stream. It occurs in normal blood plasma (plasma is the fluid fraction of blood) at a concentration of about 200 nanograms per milliliter. The total protein content of plasma is about 70 milligrams (0.070 gram) per milliliter; since a nanogram is one billionth of a gram, the total protein in plasma is 350,000 times greater than the Factor VIII:C protein in plasma. Most of the problems faced by researchers attempting to isolate Factor VIII:C were due to the amount and nature of the other proteins in the plasma.

It was known that in normal blood Factor VIII:C exists in complex association with another protein, named the "von Willebrand factor" or Factor VIII:RP (RP means "related protein"). The weight ratio of Factor VIII:C to Factor [**4] VIII:RP in normal blood is about 1:100.

Before the invention here at issue was made, scientists had succeeded in concentrating the Factor VIII:C in plasma. This concentrate has been used to replace transfusions of whole blood in the treatment of hemophilia. The process was expensive and, because of the large volume of whole [*1569] blood needed as starting material, the possibility of contamination and disease from impurities in the source blood, the large amount of extraneous plasma proteins in the concentrate, and the large volume of concentrate that still had to be administered to the patient, there has been a continuing search for improvement. The record reflects the difficulties, over decades of research, in isolating and studying Factor VIII:C. Scripps reports that Genentech's scientists had been working in the field and had not isolated human Factor VIII:C in sufficient purity and amount to conduct successful characterization experiments.

At the Scripps Clinic & Research Foundation, Dr. Zimmerman and Dr. Fulcher were studying Factor VIII:C from human and porcine blood. These scientists succeeded in isolating and, for the first time, characterizing Factor VIII:C, by a process of chromatographic [**5] absorption of the Factor VIII:C complex using monoclonal antibodies specific to Factor VIII:RP, followed by separation of the Factor VIII:C. n3 Monoclonal antibodies are produced by the cloned copies of a single hybridoma cell. A hybridoma is a hybrid cell that is immortal: that is, it does not die as do normal cells, but continues to reproduce clones that in turn produce a specific antibody. As described in the R *'011* patent, the hybridoma was made by fusing a mouse spleen cell that produced the desired antibody to Factor VIII:RP, with a mouse cancer cell, which contributed the immortality. The patent describes the method of assay for clones producing antibodies to VIII:RP, their isolation, and preparation of the monoclonal antibodies for use as the immunoadsorbent.

n3 Drs. Zimmerman and Fulcher characterized the Factor VIII:C using a technique described as SDS-gel ("SDS" stands for sodium dodecyl sulfate) electrophoresis and production of a precipitating heterologous antibody. This work was reported in Fulcher and Zimmerman, *Proc. Nat'l Acad. Sci. USA*, "Characterization of the Human Factor VIII Procoagulant Protein with a Heterologous Precipitating Antibody", Vol. 79, pp. 1648-52, March, 1982. It is not disputed that this is the first time that human Factor VIII:C was sufficiently pure to be characterized scientifically, and that the Zimmerman/Fulcher characterization is now the generally recognized "fingerprint" of Factor VIII:C.

[**6]

The claimed process whereby the Factor VIII:C/VIII:RP complex is separated from the other materials in blood, followed by separation of the VIII:C from the VIII:RP, is described in the R *'011* patent and was summarized by Scripps as follows:

> The first step involves the application of a solution containing Factor VIII complex

> (Factor VIII:C/Factor VIII:RP) to a column packed with agarose beads. Attached to the beads is a monoclonal antibody to Factor VIII:RP. The monoclonal antibody binds and immobilizes the Factor VIII:RP part of the Factor VIII complex while the non-Factor VIII materials simply pass through the column. A calcium salt solution is then applied to break the bond between the Factor VIII:C and the Factor VIII:RP. The Factor VIII:C is eluted from the column while the Factor VIII:RP remains bound to the antibody.

The procedure produces purified but dilute Factor VIII:C:

> After this first step the Factor VIII:C is highly purified, but dilute. A second step to concentrate the Factor VIII:C solution may then be performed. This involves absorbing the Factor VIII:C on an aminohexylagarose column. The Factor VIII:C on the aminohexyl column is then eluted with a very small [**7] amount of calcium salt solution, resulting in a highly concentrated solution of highly purified Factor VIII:C.

The potency and activity n4 of the fractions obtained by this technique were summarized by Scripps as follows:

> [*1570] When the Factor VIII:C is eluted from either type of column it is collected serially in a number of small, individual portions called "fractions." When the Factor VIII:C is eluted from the monoclonal antibody column, for example, the initial fractions will have little VIII:C. The VIII:C increases as the Factor VIII:C is released. After the majority of Factor VIII:C has been released, the later fractions will contain decreasing amounts.
> Table I in the Zimmerman patent contains an analysis of two individual fractions. Patent Fraction 3 has a potency of 1172 units/ml and a specific activity of 2294 units/mg. Patent Fraction 4 is from another experiment and has a potency of 545 units/ml and a specific activity of 2370 units/mg.

Issues raised in this litigation concern purified Factor VIII:C and the reliability and reproducibility of the process, as these aspects relate to the validity, enforceability, and infringement of the R *'011* patent claims.

> n4 "Potency" refers to the amount of activity in a given volume of solution. For example, if 1000 units of Factor VIII:C activity were dissolved in 1 milliliter (ml) of water, the potency of the solution would be 1000 units/ml.
>
> "Specific activity" refers to the number of units of activity for a given mass of protein. For example, if 1000 units of Factor VIII:C activity were present in 1/2 milligram (mg) of protein, the specific activity would be 2,000 units/mg.
>
> One "Unit" is defined as the activity present in 1 ml of normal plasma.

[**8]

The Claims

The claims in suit are product-by-process claims 13, 14, 17, 18, and 34, and product claims 24-29. Claim 13 is representative of the product-by-process claims:

13. Highly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1.

Claim 1 is:

> 1. An improved method of preparing Factor VIII procoagulant activity protein comprising the steps of
>
> (a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,
>
> (b) eluting the VIII:C,
>
> (c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,
>
> (d) eluting the adsorbed VIII:C, and
>
> (e) recovering highly purified and concentrated VIII:C.

Product claims 24-29 were added by reissue, and are the focus of most of the controversy:

> 24. A human VIII:C preparation having a potency in the range of 134 to 1172 units per ml, and being substantially free of VIII:RP.
> 25. A human VIII:C preparation of claim 24, wherein the VIII:C concentration is at least 160,000 fold purified relative to VIII:C in plasma. n5
> 26. A human VIII:C preparation of claim 24, [**9] wherein the ratio of VIII:C to VIII:RP is greater than 100,000 times the ratio in plasma.
> 27. A human VIII:C preparation of claim 24, wherein said VIII:C is isolated from VIII:C/VIII:RP and 90-100 percent of the VIII:RP has been removed.
> 28. A human VIII:C preparation having a specific activity greater than 2240 units/mg.
> 29. A human VIII:C preparation of claim 28 wherein the potency is in the range of 134 to 1172 units/ml.

> n5 "Fold purification" is the ratio of the specific activity of a protein sample to the specific activity of normal plasma. The Factor VIII:C specific activity of normal human plasma is known to be 0.014 units/mg. Thus the relationship is:
>
> fold purification = specific activity/0.014.
>
> For example, if a Factor VIII:C sample has a specific activity of 2240 units/mg, its fold purification value is 160,000. Stated another way, the sample is 160,000 times purer, as to Factor VIII:C, than normal plasma.

Summary Judgment

[HN1] Summary judgment is a useful procedural tool whereby an unnecessary trial [**10] is avoided when there are no material facts in dispute. However, summary proceedings are not intended to substitute for trial when it is indeed necessary to find material facts. *Meyers v. Brooks Shoe, Inc., 912 F.2d 1459, 1461, 16 U.S.P.Q.2d (BNA) 1055, 1056 (Fed. Cir. 1990)* ("the factual dispute should be reserved for trial"). A factual question is material if a reasonable jury could return a verdict for the non-moving party based at least in part on its determination of the [*1571] factual question. *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).* In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the opponent of the motion, *Poller v. Columbia Broadcasting System, Inc., 368 U.S. 464, 473, 7 L. Ed. 2d 458, 82 S. Ct. 486 (1961),* and doubts resolved in favor of the opponent. *Cantor, dba Selden Drugs Co. v. Detroit Edison Co., 428 U.S. 579, 582, 49 L. Ed. 2d 1141, 96 S. Ct. 3110 (1976).*

[HN2] A motion for summary judgment must be supported with a sufficient showing to establish that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett, 477 U.S. 317, 325, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986).* The [**11] burden of establishing entitlement to summary disposition is with the movant, with due consideration to the burden of proof. *Id.* When a sufficiently supported motion has been submitted, the burden of coming forward and showing that there is a genuine issue of material fact shifts to the non movant. The Court has observed that "all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Anderson, 477 U.S. at 249* (quoting *First National Bank of Arizona v. Cities Service Co., 391 U.S. 253, 288-289, 20 L. Ed. 2d 569, 88 S. Ct. 1575 (1968)).* However, "if the evidence is merely colorable, or is not significantly probative, summary judgment may be granted". *Anderson, 477 U.S. at 249-50* (citations omitted).

Scripps and Genentech both argue that certain issues that were decided summarily against each of them were not resolvable on summary judgment in favor of the other, if Rule 56 were correctly applied. We have concluded that the district court was correct in its determination, as to some of the issues in suit, that there were no questions of material fact; but not for all issues. [**12] For those issues that could indeed be decided summarily, we have reviewed the decision for correctness as a matter of law. For those issues on which summary judgment was inappropriately granted, we have reversed the grant and remanded for trial.

I

Inequitable Conduct and Enablement

On the basis of statements that the inventors made to the reissue examiner in connection with prosecution of the newly added product claims, issued as claims 24-29 of the R *'011* patent, the district court granted Genentech's motion for summary judgment of unenforceability of the claims based on inequitable conduct.

Although the court did not hold the claims invalid for lack of enablement, the issues of enablement and inequitable conduct were intertwined. [HN3] The "enablement" requirement is set forth in Title 35 as follows:

> *35 U.S.C. § 112* **para. 1.** The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

The purpose of this provision is to assure [**13] that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and the knowledge in the art. *See United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 U.S.P.Q.2d (BNA) 1217, 1223 (Fed. Cir. 1988), cert. denied, 490 U.S. 1046, 109 S. Ct. 1954, 104 L. Ed. 2d 423 (1989).*

During prosecution of the reissue application the patent examiner had raised various questions under § 112, relating to the purity of the Factor VIII:C that was the subject of the proposed product claims. Communications from the inventors covered such matters as the presence of fibrinogen [*1572] and fibronectin and their removal by those skilled in the art; variations in chromatographic purification results; and the determination of purity using SDS-gels. The examiner requested a showing of the mathematical relationship between specific activity and fold purification, and other data, which the inventors provided.

The reissue examiner's objection to the scope of the product claims was withdrawn on the inventors' response that they had obtained human Factor VIII:C at "levels closely approaching the theoretical [**14] limit". The inventors explained that the difference in fold purification of about 169,000 shown in Table I, and their calculation of the theoretical value of 357,000-fold, was 2-fold, from which the inventors stated that the "specification teaches those skilled in the art the production of essentially pure VIII:C." They explained that the removal of any remaining fibrinogen and fibronectin was within the skill of the art, when these impurities were identified. The examiner, apparently satisfied with the inventors' answers, n6 granted the reissue application with the added product claims as amended.

> n6 The several defendants herein all presented arguments to the examiner, in Protests filed during the reissue proceeding, on why the product claims should not be allowed.

The inventors distinguished the case of *In re Fisher, 57 C.C.P.A. 1099, 427 F.2d 833, 166 U.S.P.Q. (BNA) 18 (CCPA 1970),* which held the open-ended claims there presented unpatentable for lack of enablement of "future compositions having potencies far in excess of those obtainable [**15] from his teachings plus ordinary skill". *Id.* at 839, 166 U.S.P.Q. at 24. [HN4] Open-ended claims are not inherently improper; as for all claims their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art. They may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit. *See Fisher, supra.*

While Genentech argues that the issue is whether the inventors misrepresented the purity of their Factor VIII:C, Scripps points out that the claims do not require 100% pure VIII:C. The product-by-process claims all refer to "highly purified and concentrated" VIII:C, and the product claims contain limitations that are met by less than 100% pure VIII:C: for example, that the VIII:C is "at least 160,000 fold purified relative to VIII:C in plasma" (claim 25), that "the ratio of VIII:C to VIII:RP is greater than 100,000 times the ratio in plasma" (claim 26), that the VIII:C product has a potency of 134-1172 units/ml (claim 24) or a specific activity of over 2400 units/mg (claim 28), and is substantially free of VIII:R (claims 24-27). Indeed, the district court [**16] did not find that all these claim limitations depended on the criticized representations about purity that were made to the examiner. However, the court found that the inventors' statements about the purity of the product were unsupported by evidence, and on this basis adjudged all the claims unenforceable for inequitable conduct.

The court referred to a Declaration by Drs. Zimmerman and Fulcher, during prosecution of the reissue application, that "we have achieved purified VIII:C at levels very near what we believe to be the theoretical values with the claimed process." The court found that "Drs. Zimmerman and Fulcher made crucial factual assertions, for the purpose of reversing the Examiner's initial rejection of the open-ended purity claims, for which they had no factual support." The court stated at the hearing that the inventors made statements about purity for which they did not have evidence:

> THE COURT: . . . and without implying improper motives it is an issue [purity] on which the inventors did not seem to have evidence but without evidence they created the -- well, you say they made a square statement saying that almost always will you get pure VIII:C when, in fact, they [**17] didn't know that you would almost always get pure VIII:C.

The district court expressed its concern about the inventors' knowledge of the reliability of the process:

> THE COURT: Mr. Feiler, I'm not questioning that they got pure C, they have [*1573] gotten lots of pure C. What they did not know was what is the probability of getting VIII:Cevery time you run one of these columns. What percentage of the fractions that come out will be pure VIII:C. They just didn't know.

This reasoning is reflected in the court's finding:

> The undisputed evidence shows that (1) only some of the fractions appeared to be free of fibronectin while others were not, (2) the inventors were unable to quantify how much fibronectin the stream of the product from the column contained, and (3) the fraction on which the patent application (Table I) was based contained up to 50% fibronectin.

Scripps, 707 F. Supp. at 1557, 11 U.S.P.Q.2d at 1196.

Scripps stated that the inventors' statements to the examiner were justified, that the inventors believed them to be correct, that there was evidence before the district court that the inventors obtained gels showing essentially pure Factor VIII:C, and that the inventors obtained [**18] immunological tests showing no evidence of fibronectin or fibrinogen. Scripps argued that the inventors had the good faith belief that they had enabled the preparation of pure Factor VIII:C, and referred to evidence of contemporaneous correspondence from Dr. Zimmerman to other scientists that "We believe that purification of the human VIII:C is essentially complete". There were declarations filed with the district court, of Dr. Katzmann (a scientist at the Mayo Clinic) and Dr. Hrinda (a scientist at Rorer), that the inventors had obtained essentially pure Factor VIII:C. Dr. Katzmann also explained that Factor VIII:C activity can vary in samples having the same degree of purity; Genentech's data showed the same effect. There was deposition testimony on tests by Dr. Fulcher, showing no fibronectin.

Genentech asserts that the inventors deliberately withheld an analysis of the Table I material after the examiner requested it, and misrepresented that the impurities were "trace" when in fact the materials described in the specification contained 50% fibrinogen and fibronectin. Scripps responds that the requested analysis of the Table I material was indeed provided, that the examiner understood and [**19] was not misled by the inventors' statements about purity, that additional evidence showed that the representations made to the examiner were scientifically correct, and that, in all events, the statements were made in good faith.

The district court placed substantial weight on Dr. Zimmerman's deposition testimony that "trace contaminants" fibrinogen and fibronectin remained, that he "did not have numbers for upper limits", and that "it is a trivial matter to remove the fibrinogen and fibronectin once they have been identified". The court commented that "Dr. Fulcher in her deposition was unable to quantify [the term 'essentially pure'] or the term 'highly purified'", and remarked that it is "impossible to extrapolate from one or several Laurells [tests of a fraction of the column stream] as to the degree of purity of the entire output". The court criticized these scientific facts as legal inadequacies.

The court appeared to require greater scientific precision than did any of the scientists whose testimony was presented. The statute, however, is directed to persons of skill in the field of the invention. Indeed, Genentech provided no evidence that one of skill in the field of this [**20] invention could not make and use a product satisfying all the limitations of the claims, by following the inventors' disclosure and the knowledge of the art. Neither evidence nor expert opinion to this effect was offered.

[HN5] The materiality of a representation, and whether the representation was made with intent to deceive or mislead, are the two essential factual predicates to determination of inequitable conduct. *Modine Mfg. Co. v. Allen Group, Inc., 917 F.2d 538, 541, 16 U.S.P.Q.2d (BNA) 1622, 1624 (Fed. Cir. 1990).* The district court stated that the "three elements of inequitable conduct" are "material prior information, chargeable to applicant, not disclosed to the PTO". *Scripps, 707 F. Supp. at 1557, 11 U.S.P.Q.2d at 1196.* Notably missing is the element of [*1574] intent, essential as a matter of law to a ruling of inequitable conduct. *See Kingsdown Medical Consultants, Ltd., v.*

Hollister, Inc., 863 F.2d 867, 876, 9 U.S.P.Q.2d (BNA) 1384, 1392 (Fed. Cir. 1988). Conduct that requires forfeiture of all patent rights must be deliberate, and proved by clear and convincing evidence. While Genentech argues that absence of reference by the court to intent does not mean that the court did not find intent, [**21] the court's remark that it was "without implying improper motives [to the inventors]" contravenes this argument. Even were the inventors' statements concerning purity in error, a finding of disputed fact that is not appropriate on summary judgment, the absence of a finding of intent to deceive or mislead the examiner precludes summary judgment of inequitable conduct. *See KangaROOS U.S.A., Inc. v. Caldor, Inc., 778 F.2d 1571, 1573, 228 U.S.P.Q. (BNA) 32, 35-36 (Fed. Cir. 1985)* (a disputed question of intent to deceive is not appropriate for summary resolution).

The grant of partial summary judgment of unenforceability of the R *'011* claims for inequitable conduct is reversed.

Scripps had filed a cross-motion for summary judgment on this issue. This does not, of itself, require adjudication in its favor. *United States v. Fred A. Arnold, Inc., 573 F.2d 605, 606 (9th Cir. 1978); accord, Cram v. Sun Insurance Office, Ltd., 375 F.2d 670, 673-74 (4th Cir. 1967)* ("The [HN6] fact that both sides moved for summary judgment does not establish that there is no issue of fact and require that judgment be granted for one side or the other"). These disputed factual questions of materiality and intent, which [**22] depend on the assessment of scientific facts as well as on the credibility of witnesses, are not amenable to summary resolution. The issue is remanded for trial.

II

35 U.S.C. § 251

A

The R *'011* patent is a reissue of Patent No. 4,361,509 ("the '509 patent"), granted on November 20, 1982. Genentech challenged the adequacy of the patentee's reason for seeking reissue, stating that this reason was insufficient in terms of *35 U.S.C. § 251*. On this ground the district court granted Genentech's motion for partial summary judgment of invalidity of claims 17, 18, 24-29, and 34.

Although there were factual aspects debated by the parties, they are not material to the question of the legal adequacy of the patentee's reason for requesting reissue. [HN7] That is a question of law, and the facts material to that question were not in dispute. The matter could have been, and was, decided summarily. *See Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys., 804 F.2d 659, 662, 231 U.S.P.Q. (BNA) 649, 651 (Fed. Cir. 1986), cert. denied, 480 U.S. 933, 94 L. Ed. 2d 764, 107 S. Ct. 1573 (1987)* ("These facts are not in dispute, though their legal significance is. Thus the basis on which the district court decided the question was amenable [**23] to summary judgment"). However, the district court erred in its conclusion of law.

[HN8] The reissue statute provides in part:

> ***35 U.S.C. § 251***. Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall . . . reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application. . . . No new matter shall be introduced into the application for reissue.

In accordance with *37 C.F.R. § 1.175(a)(5)* and (a)(3) [HN9] the applicant for reissue must "specify[] the errors relied upon, and how they arose or occurred," and must "distinctly specify[] the excess or insufficiency in the claims"; and in accordance with *37 C.F.R. § 1.175(a)(6)* the applicant must declare the absence of deceptive intention.

The principal error that the inventors sought to cure was the claiming of "less than [they] had a right to claim in the patent" due to the omission of product claims. The '509 patent contained only process [*1575] and product-by-process [**24] claims. n7 In the reissue application inventors Zimmerman and Fulcher declared that they had always viewed the Factor VIII:C product as their invention, pointing out that the '509 specification stated that it was an object of their invention to produce highly purified Factor VIII:C.

> n7 [HN10] Broadened claims by reissue must be applied for within two years of grant of the original patent. *35 U.S.C. § 251*. This requirement was met.

----------End Footnotes---------- [HN11] -

An error of law is not excluded from the class of error subject to correction in accordance with the reissue statute. Although attorney error is not an open invitation to reissue in every case in which it may appear, *see In re Weiler, 790 F.2d 1576, 1579, 229 U.S.P.Q. (BNA) 673,*

675 (Fed. Cir. 1986) ("not every event or circumstance that might be labeled 'error' is correctable by reissue"), the purpose of the reissue statute is to avoid forfeiture of substantive rights due to error made without intent to deceive. *See generally Ball Corp. v. United States, 729 F.2d 1429, 1939 n.28,* [**25] *221 U.S.P.Q. (BNA) 289, 296 n.28 (Fed. Cir. 1984)* (the reissue statute "is based on fundamental principles of equity and fairness").

When the statutory requirements are met, reissuance of the patent is not discretionary with the Commissioner; it is mandatory ("shall"). *See In re Handel, 50 C.C.P.A. 918, 312 F.2d 943, 948, 136 U.S.P.Q. (BNA) 460, 464 (CCPA 1963)* ("the whole purpose of the statute, so far as claims are concerned, is to permit limitations to be added to claims that are too broad or to be taken from claims that are too narrow").

Genentech does not dispute that error was made, and does not challenge the principle of the availability of product claims to the purified Factor VIII:C. Further, Genentech does not assert that the attorneys' initial view of the unavailability of product claims involved any deceptive intention. The district court, holding that there was insufficient reason for reissue, appeared to interpret § 251 as requiring a showing that the error in claiming the product could not have been avoided, in order to be eligible for cure. This is not the framework of the reissue statute.

[HN12] The law does not require that no competent attorney or alert inventor could have avoided the error sought to be corrected by reissue. [**26] Failure of the attorney to claim the invention sufficiently broadly is "one of the most common sources of defects". *In re Wilder, 736 F.2d 1516, 222 U.S.P.Q. (BNA) 369 (Fed. Cir. 1984), cert. denied, 469 U.S. 1209, 84 L. Ed. 2d 323, 105 S. Ct. 1173 (1985):*

> An attorney's failure to appreciate the full scope of the invention is one of the most common sources of defects in patents. The fact that the error could have been discovered at the time of prosecution with a more thorough patentability search or with improved communication between the inventors and the attorney does not, by itself, preclude a patent owner from correcting defects through reissue.

Id. at 1519, 222 U.S.P.Q. at 371.

[HN13] Subjective intent is not determinative of whether the applicants erred in claiming less than they had a right to claim. *In re Mead, 581 F.2d 251, 255, 198 U.S.P.Q. (BNA) 412, 416 (CCPA 1978).* "Intent to claim" is not the criterion for reissue, and has been well described as "but judicial shorthand, signifying a means of measuring whether the statutorily required *error* is present." *In re Weiler, 790 F.2d 1576, 1581, 229 U.S.P.Q. (BNA) 673, 676 (Fed. Cir. 1986)* (emphasis in original). The statutory standard of reissuable error is objective, and [**27] does not require proof of subjective state of mind:

> Determining what protection [an inventor] intended to secure by [an] original patent for the purposes of § 251 is an essentially factual inquiry confined to the *objective* intent manifested by the original patent.

In re Rowand, 526 F.2d 558, 560, 187 U.S.P.Q. (BNA) 487, 489 (CCPA 1975) (emphasis in original).

On undisputed facts, the inventors established that they had claimed less than they had a right to claim, that they had [*1576] done so in error, and that there was not deceptive intention. The application for reissue fully complied with the statutory and regulatory requirements. n8

> n8 The patent examiner and the PTO Office of Quality Review found that the applicant adhered to correct reissue practice, pursuant to Manual of Patent Examining Procedure § 1456 (Rev. 3, 1986).

As a matter of law, reissue claims 17, 18, 24-29, and 34 are not invalid on this ground. The grant of partial summary judgment is reversed. On remand, partial summary judgment shall be entered for [**28] Scripps on this ground.

B

The district court had also held the reissue product claims invalid for inadequate support in the specification for their open-ended scope, referring to changes that Drs. Zimmerman and Fulcher made in the text of the specification during the drafting process. For example, they changed "virtually pure" to "highly purified"; and inserted "largely" before "free of contaminants". This is an issue of enablement, which is not challenged by Genentech; but it also raises questions of claim interpretation in light of the specification. In view of the several disputed questions of material fact underlying these issues, see Part I *ante* and Part V *post*, summary judgment on this ground was improper, and the grant thereof is reversed. This issue, also, requires trial.

III

Anticipation

The district court held, on cross-motions for summary judgment, that "it had been proved by clear and convincing evidence" that claims 24, 26, and 27 were invalid for anticipation, *35 U.S.C. § 102*(b), based on subject matter described in a 1979 dissertation by Robert B. Harris entitled "Isolation and Characterization of Low Molecular Weight, Non-Aggregated Antihemophilic Factor [**29] from Fresh Human Plasma".

A

[HN14] Anticipation is a question of fact. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 619, 225 U.S.P.Q. (BNA) 634, 637* (Fed. Cir.), *cert. dismissed, 474 U.S. 976, 88 L. Ed. 2d 326, 106 S. Ct. 340 (1985).* To make such finding on summary judgment, the court must determine that no facts material to the question are disputed; or that even if all material factual inferences are drawn in favor of the non-movant, there is no reasonable basis on which the non-movant can prevail. *Cooper v. Ford Motor Co., 748 F.2d 677, 679, 223 U.S.P.Q. (BNA) 1286, 1288 (Fed. Cir. 1984).* The standard of proof that would have to be met at trial must be considered. *Anderson, 477 U.S. at 257.*

[HN15] Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. *Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 138, 231 U.S.P.Q. (BNA) 644, 646 (Fed. Cir. 1986); RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 1444, 221 U.S.P.Q. (BNA) 385, 388 (Fed. Cir. 1984).* There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.

It is [**30] sometimes appropriate to consider extrinsic evidence to explain the disclosure of a reference. Such factual elaboration is necessarily of limited scope and probative value, for a finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. [HN16] The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference. *See Studiengesellschaft Kohle, mb H v. Dart Industries, Inc., 726 F.2d 724, 727, 220 U.S.P.Q. (BNA) 841, 842 (Fed. Cir. 1984)* (although additional references may serve to reveal what a reference would have meant to a person of ordinary skill, it is error to build "anticipation" on a combination [*1577] of these references). If it is necessary to reach beyond the boundaries of a single reference to provide missing disclosure of the claimed invention, the proper ground is not § 102 anticipation, but § 103 obviousness. Indeed, a publication on the Harris dissertation was included [**31] in the prior art statement filed by Scripps and was a cited reference under § 103.

B

In the summary judgment proceedings the parties filed three successive declarations of Dr. Harris, each explaining his dissertation. In the first declaration, filed by Miles, Inc., Harris stated that he isolated "a low molecular weight antihemophilic factor". In his second ("supplemental") declaration, filed by Scripps, Harris described this factor as not a naturally occurring substance, and of low specific activity:

> 6. The material I identified as low molecular weight antihemophilic factor (LMW-AHF) was not a naturally occurring substance. The material of my dissertation is the result of reacting plasma with a reducing agent called dithiothreitol (DTT) prior to purification. The reduced plasma is run through an initial purification step, and is then chemically reacted with radioactively labeled iodoacetamide (<14>C-IAA). This reduced and alkylated material was the LMW-AHF reported in my dissertation. After further purification, I obtained a maximum specific activity of 59.1 [units]/mg.

In the third Harris declaration, filed by Miles, Harris stated that his dissertation

> accurately reports [**32] on my work in which I was able to, and did, obtain a human VIII:C preparation having a potency of 193 [units]/ml and being substantially free of VIII:RP, the ratio of VIII:C to VIII:RP being greater than 100,000 times the ratio in plasma.

The third Harris declaration was cited by the district court in support of its finding of anticipation.

The parties debate whether Harris' statement in his second declaration that his product was chemically changed from naturally occurring VIII:C, is contradicted by the statement in his third declaration that he obtained a human VIII:C preparation. Scripps also points out that neither the potency value nor the ratio of VIII:C to VIII:RP described in the third Harris declaration appears

in the Harris dissertation. Nor does the gel pattern evidence on which the district court found that:

> Harris also based his identification of his preparation upon sodium dodecyl sulfate polyacrylamide gel electro-phoresis (SDS-PAGE) tests [the same tests used by Dr. Fulcher]. While Harris' gel patterns do not match the gel pattern found by Dr. Fulcher, there is no evidence that if he had VIII:C, it would necessarily have the gel pattern found by Dr. Fulcher.

[**33] *Scripps, 707 F. Supp. at 1551 n.6, 11 U.S.P.Q.2d at 1190 n.6.* Further, this finding that human Factor VIII:C, if obtained by Harris, would not necessarily have the "fingerprint" gel pattern of Dr. Fulcher, was not simply an adverse factual inference, improper on summary judgment; it was a finding of scientific fact contrary to the evidence. This finding also appears to be inconsistent with the court's finding that Dr. Harris had obtained purified Factor VIII:C because he based his identification on the same tests and gel patterns taught by Zimmerman and Fulcher. Also contradicting the court's conclusion was Scripps' evidence that the human Factor VIII:C SDS-gels of the inventors, the defendants, and non-parties to the litigation were the same, and that Dr. Harris' gel patterns were different.

Scripps contends that the court also erred in taking Dr. Harris' assertion in his third declaration that he obtained a potency of 193 units/ml and then construing the dissertation so as to find support for it. The court found support for this potency by combining (1) the potency of 2.7 units/ml reported by Harris for the sample in his Figure 9 with (2) the 71-fold concentration of an unidentified [**34] sample described on page 56 of the dissertation, and then multiplying 2.7 by 71 to obtain a potency of 191.7 units/ml. This combination of data is contrary to the statement of Dr. Harris in his second declaration that:

> [*1578] 15. Neither is there any information from which to infer that the LMW-AHF recovered in the experiment represented by Figure 9 was the subject of [the page 56] lyophilization and reconstitution experiment.

Scripps also states that the maximum potency that the dissertation disclosed was 10 units/ml. Even crediting Dr. Harris' assertion that the ratio of AHF (antihemophilic factor) to VWF (von Willebrand factor) may have been as high as 100,000:1, Scripps calculated that this would only increase the potency of the concentrated sample on Harris' page 56 to a maximum of 10.0 units/ml. A sample having the potency of 191.7 units/ml, the value found by the district court, was calculated by Scripps to have a theoretical ratio of no less than 1,917,000:1, over 19 times higher than that asserted by Dr. Harris in his dissertation. Scripps thus argues that the court's findings are contrary to the evidence. We need not decide the correctness of these calculations and their premises, [**35] for it is clear that these issues, on which there was conflicting evidence, were not subject to summary resolution.

To the extent that apparent inconsistencies among the three Harris declarations raise questions of credibility and weight, whether of witness or of interpretation of scientific data, they were improperly resolved on summary judgment. *Agosto v. INS, 436 U.S. 748, 756, 56 L. Ed. 2d 677, 98 S. Ct. 2081 (1977); Poller, 368 U.S. at 473.* [HN17] In patent cases, questions by affidavit is disfavored. *See Poller v. Columbia Broadcasting System, Inc., 368 U.S. 464, 473, 7 L. Ed. 2d 458, 82 S. Ct. 486 (1961); United States v. Fred A. Arnold, Inc., 573 F.2d 605, 606 (9th Cir. 1978).* Trial by document is an inadequate substitute for trial with witnesses, who are subject to examination and cross-examination in the presence of the decision-maker. *Sartor v. Arkansas Natural Gas Corp., 321 U.S. 620, 628, 88 L. Ed. 967, 64 S. Ct. 724 (1944).*

Scripps also raised the question of whether the Harris dissertation was enabling and placed the purported anticipatory teaching of purified Factor VIII:C in possession of the public. Scripps pointed out that Data in Harris' third declaration, on which the court relied, do not appear in his dissertation or in any other reference. [**36] *See Akzo N.V. v. United States Int'l Trade Comm'n, 808 F.2d 1471, 1479, 1 U.S.P.Q.2d (BNA) 1241, 1245 (Fed. Cir. 1986), cert. denied, 482 U.S. 909, 96 L. Ed. 2d 382, 107 S. Ct. 2490 (1987)* (anticipatory reference must be enabling); *In re Brown, 51 C.C.P.A. 1254, 329 F.2d 1006, 1011, 141 U.S.P.Q. (BNA) 245, 249 (CCPA 1964).* The need to consider this issue, on disputed factual premises, also negates the propriety of the grant of summary judgment based on anticipation.

The grant of partial summary judgment of invalidity of claims 24, 26, and 27 for anticipation by the Harris dissertation is reversed. The issue is not amenable to summary disposition, and is remanded for trial.

IV

Best Mode

The district court granted Genentech's motion for summary judgment that claims 13, 14, 17, 18, 24-29, and

34 are invalid for failure to comply with the "best mode" requirement of [HN18] *35 U.S.C. § 112:*

> § **112**. The specification shall . . . set forth the best mode contemplated by the inventor of carrying out his invention.

[HN19] Compliance with the best mode requirement is a question of fact, and invalidity for failure of compliance requires proof by clear and convincing evidence that the inventor knew of and concealed a better mode of carrying out the invention [**37] than was set forth in the specification. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1369, 1379, 231 U.S.P.Q. (BNA) 81, 90 (Fed. Cir. 1986), cert. denied, 480 U.S. 947, 94 L. Ed. 2d 792, 107 S. Ct. 1606 (1987).*

The concealment asserted by Genentech relates to the monoclonal antibodies that bind the Factor VIII complex in the initial step of separation from plasma. Genentech did not dispute that the specification describes the inventors' preferred method of obtaining these monoclonal antibodies. [*1579] The specification describes the process, starting with injection into mice of the commercial Factor VIII concentrate, to produce antibodies against Factor VIII:RP; the preparation of the hybridomas and their screening for the desired antibodies; and the method of evaluation of the antibody's ability to bind Factor VIII:RP in the presence of salt solution that disassociates Factor VIII:C. The specification describes the properties for which the antibodies were screened, *viz.* to obtain a monoclonal antibody to Factor VIII:RP, of the IgG class, which binds greater than 90% of the VIII:RP out of plasma or concentrate, and which remains bound to the VIII:RP during saline elution of Factor VIII:C.

None of this [**38] was criticized by Genentech. There was no charge of concealment of special manipulations, or undisclosed techniques. Genentech's argument is primarily that because of the laborious nature of the process of screening monoclonal antibodies, the inventors should have voluntarily placed in a depository and made available to the public the antibody to Factor VIII:RP designated 2.2.9, which was the first effective antibody obtained by Scripps' screening, and was used by Scripps in carrying out the claimed invention.

Scripps states that the procedures in the specification produce monoclonal antibodies having the characteristics set forth in the specification, that the process of obtaining these antibodies was fully disclosed, that the data in Table I are for the 2.2.9 antibody, and that the 2.2.9 antibody was not concealed. Scripps agreed that the 2.2.9 antibody was indeed the first that had the described properties, and states that three out of the first seven antibodies screened had these properties, all obtained by routine and admittedly time-consuming procedures. It was not disputed that the inventors obtained the 2.2.9 antibody by following the procedures in the patent specification, [**39] and that these were the inventors' preferred procedures.

The district court found that the inventors concealed the 2.2.9 antibody, and that this antibody was the best mode of carrying out the invention. The court did not hold that deposit of the 2.2.9 antibody was required, although the court stated that a person of skill in the art would not have known "where to obtain it". The court made no other finding relating to concealment.

A deposit was not required by the PTO during examination of either the '509 or the R *'011* patents. *See* M.P.E.P. § 608.01(p)(C)(3). Nor does Genentech argue that deposit was obligatory. No protester raised the issue of deposit in connection with the reissue application. Although Genentech suggests that Scripps should have made a deposit voluntarily, failure to do so can not constitute legal or factual basis for patent invalidity.

Despite the extensive attorney argument, there were no material facts in dispute. There was no evidence by Genentech that the antibodies used by Drs. Zimmerman and Fulcher differed from those obtainable according to the process described in the specification. The laborious nature of this work was recognized in *Hybritech, supra,* [**40] and again in *In re Wands, 858 F.2d 731, 737-38, 8 U.S.P.Q.2d (BNA) 1400, 1406-07 (Fed. Cir. 1988).* In *Wands* this court, considering the question of enablement, declined to require the deposit of antibody samples that could be obtained by screening following the procedures in the specification.

Genentech had argued to the PTO, in its Protest against the reissue application, that the process is "easily" carried out to produce "high affinity monoclonal antibodies":

> There are numerous references demonstrating the ease with which high affinity monoclonal antibodies could be obtained to Factor VIII:R[P].

In the context of best mode, on facts similar to those at bar, this court's holding in *Hybritech* settled the issue:

> The only evidence even colorably relating to concealment is testimony by various Hybritech employees that sophisticated, competent people perform the screening

> and that the screening process is labor-intensive and time-consuming. *It is not plausible that this evidence amounts to proof of concealment* of a best mode for [*1580] screening or producing monoclonal antibodies for use in the claimed '110 process, and therefore we are of the firm conviction that the district court's [**41] finding that the best mode requirement was not satisfied is clearly erroneous.

Hybritech, 802 F.2d at 1385, 231 U.S.P.Q. at 94 (emphasis added). Applying *Hybritech* to the undisputed facts, a finding of concealment can not be supported. The claims were incorrectly held invalid on this ground.

As a matter of law, we reverse the grant of partial summary judgment that claims 13, 14, 17, 18, 24-29, and 34 are invalid for failure to meet the best mode requirement. We remand with instructions that partial summary judgment be entered for Scripps on this ground.

V

Infringement

The district court found the R *'011* product claims 24, 25, 28, and 29 literally infringed, explaining that "Human factor VIII:C as claimed in the [product claims] therefore applies to any Factor VIII:C preparation, regardless of how produced, having the same material structural and functional characteristics as the plasma-derived preparation." The court did not distinguish between plasma-derived and recombinantly-produced human Factor VIII:C. n9 Genentech does not challenge this ruling as applied to plasma-derived VIII:C.

> n9 In accordance with the recombinant procedure, the human Factor VIII:C gene is identified, isolated, and inserted into a host cell, where it is replicated and from which Factor VIII:C is expressed and excreted into a culture medium. From this medium it is further purified using, *inter alia*, monoclonal antibodies to Factor VIII:C.

[**42]

A

Genentech appeals the district court's grant of Scripps' motion for summary judgment that the product claims are infringed by Genentech's recombinantly-produced human Factor VIII:C. Genentech states that the product claims should be construed, as a matter of law, to avoid infringement by recombinant VIII:C. Alternatively, Genentech argues that infringement is avoided by application of the reverse doctrine of equivalents. These two theories of non-infringement require different analytic approaches.

In "claim construction" the words of the claims are construed independent of the accused product, in light of the specification, the prosecution history, and the prior art. Of course the particular accused product (or process) is kept in mind, for it is efficient to focus on the construction of only the disputed elements or limitations of the claims. However, the construction of claims is simply a way of elaborating the normally terse claim language: in order to understand and explain, but not to change, the scope of the claims.

We described the workings of claim construction in *Tandon Corp. v. Int'l Trade Comm., 831 F.2d 1017, 1021, 4 U.S.P.Q.2d 1283, 1286 (Fed. Cir. 1987):*

> [HN20] Claim [**43] interpretation is a question of law, having factual underpinnings. When the meaning of key terms of claims is disputed . . . extrinsic evidence may be adduced including testimony of witnesses, and reference may be had to the specification, the prosecution history, prior art, and other claims.

Genentech argues that the term "a human VIII:C preparation" in the R *'011* product claims should be construed as limited to the Factor VIII:C obtained by separation from plasma. In essence, Genentech argues that these claims should be construed as carrying an inherent process limitation, on the basis that Scripps did not invent human Factor VIII:C, or discover its structure, or its properties as the coagulant factor in blood, but simply the process of purifying it to a higher degree of purity than was heretofore available. However, Genentech also states that it is not challenging the propriety of product claims to Factor VIII:C; and it did not do so before the district court. While judicial attention has on occasion focused on the patentability of claims in this context, *see, e.g., In re Bergstrom, 57 C.C.P.A. 1240, 427 F.2d 1394, 166 U.S.P.Q. (BNA) 256 (CCPA 1970),* Genentech, by conceding that [*1581] the product claims were [**44] appropriately granted, presents inconsistent legal arguments. Genentech has not supported, as a matter of law, its requested claim construction.

B

[HN21] The so-called "reverse doctrine of equivalents" is an equitable doctrine invoked in applying properly construed claims to an accused device. Just as the purpose of the "doctrine of equivalents" is to prevent "pirating" of the patentee's invention, *Graver Tank & Mfg. Co. v. Linde Air Prod. Co., 339 U.S. 605, 607, 608, 85 U.S.P.Q. (BNA) 328, 330, 94 L. Ed. 1097, 70 S. Ct. 854, reh'g denied, 340 U.S. 845, 95 L. Ed. 620, 71 S. Ct. 12 (1950),* so the purpose of the "reverse" doctrine is to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention.

[HN22] The reverse doctrine of equivalents flows from the Supreme Court's statement in *Graver Tank* that an accused article may avoid infringement, even if it is within the literal words of the claim, if it is "so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way." *339 U.S. at 608-09, 85 U.S.P.Q. at 330.* Application of the doctrine requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims, which [**45] in turn is determined in light of the specification, the prosecution history, and the prior art.

The record contained evidence of the properties of plasma-derived and recombinantly produced VIII:C, which was presented primarily by Scripps in connection with its proofs of infringement. There was deposition testimony that there were differences between VIII:C from plasma and VIII:C obtained by recombinant techniques; a Scripps' witness described the products as "apples and oranges", referring specifically to stability and formulations. The parties disputed, in connection with the summary judgment motions, the capabilities of the respective processes in terms of the purity and specific activities that were enabled for the respective products. The record on this point is extensive.

Genentech argues that its product is equitably seen as changed "in principle", particularly when viewed in the context of the prior art. Genentech asserts that the specific activities and purity that are obtainable by recombinant technology exceed those available by the Scripps process; an assertion disputed by Scripps, but which if found to be correct could provide -- depending on the specific facts of similarities [**46] and differences -- sufficient ground for invoking the reverse doctrine. These aspects were not discussed by the district court.

The principles of patent law must be applied in accordance with the statutory purpose, and the issues raised by new technologies require considered analysis. Genentech has raised questions of scientific and evidentiary fact that are material to the issue of infringement. Consideration of extrinsic evidence is required, and summary judgment is inappropriate. *See C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc., 911 F.2d 670, 673, 15 U.S.P.Q.2d (BNA) 1540, 1542 (Fed. Cir. 1990).*

The grant of summary judgment of infringement of claims 24, 25, 28, and 29 is reversed. The issue requires trial.

VI

Inducement to Infringe

The district court held that Genentech induced Cutter Laboratories to infringe claims 24, 25, 28, and 29 of the R *'011* patent, *35 U.S.C. § 271*(b), through the use of both plasma-derived and recombinant Factor VIII:C. The court held:

> There is no question that Genentech delivered to Cutter materials found to have infringed, including recombinant and plasma-derived human Factor VIII:C, with the intent that Cutter itself would [develop recombinant [**47] Factor VIII:C]. . . . There is also no doubt that Genentech intended Cutter to use plasma-derived Factor VIII:C manufactured by both Genentech and Cutter which has been found to infringe.

[*1582] *Scripps, 666 F. Supp. at 1394, 3 U.S.P.Q.2d at 1493.* The facts of the relationship between Genentech and Cutter were undisputed.

Genentech states that the district court made no specific finding of direct infringement by Cutter, a predicate to a finding of inducement to infringe. Cutter is a division of Miles, a defendant herein, and is subject to the district court's finding of infringement. Thus the court's ruling on inducement was correct, as a matter of law. Subject to our holding in Part V, the decision of the district court on this issue is affirmed.

VII

Inequitable Conduct based on the Meyer Abstract

Genentech appeals the district court's grant of summary judgment that Scripps did not engage in inequitable conduct, during examination of the application that led to the '509 patent, based on a reference authored by Meyer, Obert, Zimmerman, and Edgington entitled *Monoclonal Antibodies Specific for Factor VIII from Cellular Hybrids*, No. 395 ("the Meyer abstract").

The district court [**48] observed that the Meyer abstract was cumulative to the complete Meyer paper it summarized:

> The Meyer abstract was also cited in a paper authored, *inter alia*, by Dr. Meyer herself that was submitted by Scripps to the PTO as reference RS. . . . In contrast to the Meyer abstract, which is only one paragraph long, reference RS is 27 pages in length and much more elaborate in its disclosure . . . .

Scripps, 666 F. Supp. at 1399-1400, 3 U.S.P.Q.2d at 1496. [HN23] A reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct. *Halliburton Co. v. Schlumberger Technology Corp., 925 F.2d 1435, 1440, 17 U.S.P.Q. 2d (BNA) 1834 (Fed. Cir. 1991).*

The Meyer abstract was before the patent examiner who, according to Genentech, discovered it "on his own". When a reference has been considered by the examiner, it is not controlling how it came to the examiner's attention. The complete Meyer paper, and several other references, cited the Meyer abstract. Genentech argues that Scripps should nonetheless have brought the Meyer abstract to the examiner's specific attention, in addition to having listed the complete Meyer [**49] paper in Scripps' prior art statement. [HN24] When a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it can not be deemed to have been withheld from the examiner.

Genentech presses the argument that the district court erred because the Meyer abstract was a "statutory bar", by which Genentech explains that it was published more than a year before the patent's filing date. Genentech does not explain how this was error, for the district court, like the PTO, treated as prior art both the 27-page Meyer paper and the Meyer abstract. Genentech's argument that the full paper "was not effective prior art" is contrary to law and fact, for it was published before the filing date of Scripps' '509 patent application and Scripps did not attempt to antedate the Meyer paper. It is thus immaterial when the Meyer abstract was published.

Genentech also charged Scripps with inequitable conduct because Scripps originally sought claims to its monoclonal antibodies to Factor VIII:RP, and cancelled these claims after the examiner required Scripps to provide comparative data with the monoclonal antibodies described in the Meyer abstract and other references. [**50] While Genentech argues that obtaining such data was not the burden that Scripps said it was, this is irrelevant to the issue of inequitable conduct. An applicant has the absolute right to decline to do work suggested by the PTO, and to withdraw claims that had been presented for examination, without incurring liability for inequitable conduct.

The district court reviewed the Meyer abstract's content and found, without challenge on this appeal, that:

> [*1583] The Meyer et al. abstract contains no disclosure of the purification of Factor VIII:C. The Meyer et al. abstract contains no disclosure indicating that any of the monoclonal antibodies could be bound to substrate particles to form an immunoadsorbent for isolation and purification of VIII:C from the VIII:C/VIII:RP complex.

The court concluded:

> Lacking such disclosure, the Meyer et al. abstract does not appear material to the examination of the claims that were presented in applicants' original application and issued in Patent No. 4,361,509.

Scripps, 666 F. Supp. at 1398, 3 U.S.P.Q.2d at 1495. No error is ascribed to this conclusion. [HN25] A reference that is material only to withdrawn claims can not be the basis of a holding of inequitable [**51] conduct. *Kimberly-Clark Corp. v. Johnson & Johnson Co., 745 F.2d 1437, 1457, 223 U.S.P.Q. (BNA) 603, 616-17 (Fed. Cir. 1984).*

[HN26] The party with the burden of proof of inequitable conduct must meet the clear and convincing standard. *FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1417 n.11, 5 U.S.P.Q.2d (BNA) 1112, 1117 n.11 (Fed. Cir. 1987).* Genentech did not offer evidence or legal argument whereby, even drawing all factual inferences in its favor, this standard could be met at trial, as to either materiality of the Meyer abstract, or intent to deceive or mislead. The district court's grant of partial summary judgment of no inequitable conduct based on the Meyer abstract is affirmed.

VIII

Infringement of the Product-by-Process Claims

Scripps appeals the district court's refusal to grant its motion for summary judgment of infringement of the R

'011 product-by-process claims 13, 14, 17, 18, and 34. The district court denied Scripps' motion under Rule 59(e) to amend the judgment to rule on this question. Genentech argues that this denial is not appealable, and has moved for dismissal. [HN27] Looking to the law of the Ninth Circuit, an appeal from a final judgment may include challenges to "all rulings which [**52] produced the judgment". *Munoz v. Small Business Administration, 644 F.2d 1361, 1364 (9th Cir. 1981). See Moran v. Aetna Life Insurance Co., 872 F.2d 296, 301 (9th Cir. 1989)* (denial of a summary judgment motion is appealable after entry of final judgment); 10 C. Wright, A. Miller, and M. Kane, *Federal Practice & Procedure* § 2715 (2d ed. 1983). The issue is reviewable, but on an undeveloped record we consider only the questions of law.

Scripps charges that Genentech's recombinantly-produced Factor VIII:Cinfringes the product-by-process claims, either literally or by application of the doctrine of equivalents. The district court remarked that the product-by-process claims would not be infringed unless the same process were practiced. Scripps correctly points out that this statement appears to diverge from our precedent, recognizing that this precedent arose in the context of patent prosecution, not patent infringement. *E.g., In re Thorpe, 777 F.2d 695, 227 U.S.P.Q. (BNA) 964 (Fed. Cir. 1985)* (holding that prior art pertinent only to product is proper ground for rejecting product-by-process claims); *In re Brown, 59 C.C.P.A. 1036, 459 F.2d 531, 535, 173 U.S.P.Q. (BNA) 685, 688 (CCPA 1972)* (in product-by-process [**53] claims the patentability of the product must be established independent of the process); *In re Bridgeford, 53 C.C.P.A. 1182, 357 F.2d 679, 682 n.5, 149 U.S.P.Q. (BNA) 55, 58 n.5 (CCPA 1966)* (recognizing that some courts in infringement litigation have construed product-by-process claims as limited to the particular process, but holding that patentability is determined independent of the process). In determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of [HN28] product-by-process claims is that they are not limited to product prepared by the process set forth in the claims. Thus, these claims are subject to an infringement analysis similar to that described in Part V, [*1584] *ante*. Infringement of the product-by-process claims may be considered at trial.

IX

Attorney Fees

The district court held that this was an exceptional case under *35 U.S.C. § 285, 724 F. Supp. 690,* apparently due to the court's rulings on inequitable conduct and failure to comply with the best mode. Holdings under § 285 are reviewed for abuse of the trial court's discretionary authority, considering the court's findings [**54] and conclusions and any other appropriate factors. *See Reactive Metals & Alloys Corp. v. ESM, Inc., 769 F.2d 1578, 1583, 226 U.S.P.Q. (BNA) 821, 824 (Fed. Cir. 1985).* In view of our reversal of the grants of summary judgment on the issues of best mode and inequitable conduct, the award of attorney fees flowing therefrom must be vacated. *See State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1238, 224 U.S.P.Q. (BNA) 418, 426 (Fed. Cir. 1985)* (reversing ground for holding case exceptional and accompanying award of attorney fees).

X

Other Issues

We have not repeated all the arguments and issues raised by both sides, including charges of frivolity, misstatement, and worse. Encumbered by the summary nature of the proceedings, neither scientific nor evidentiary truth has risen easily to the surface. However, we *DENY* Scripps' motion for sanctions against Genentech for filing a frivolous cross-appeal, for some of the issues raised were not clearly hopeless in law and fact. We also *DENY* each side's motions to strike various materials filed and to dismiss issues raised by the other.

Costs

Each party shall bear its costs.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, AND REMANDED [**55]

LEXSEE

ATLAS POWDER COMPANY, Plaintiff, and HANEX PRODUCTS, INC., Plaintiff-Appellant, v. IRECO INCORPORATED and ICI EXPLOSIVES USA, INC., Defendants-Appellees.

99-1041

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

190 F.3d 1342; 1999 U.S. App. LEXIS 21394; 51 U.S.P.Q.2D (BNA) 1943

September 7, 1999, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court for the District of Wyoming. Chief Judge Alan B. Johnson.

DISPOSITION: AFFIRMED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant, as successor patent licensee, challenged United States District Court for District of Wyoming bench trial determination of invalidity of original and reissue patents as anticipated by two other patents.

OVERVIEW: A patent and its reissue (patents) declared invalid by the court involved explosive compositions. To address shortcomings in detonation, explosive experts developed water-in-oil emulsions that dissolved an oxidizer into water and then dispersed the solution in oil. The patents claimed composite explosives made from the combination of a particular blasting composition and an unsensitized water-in-oil emulsion. These were identical to blasting compositions of prior art issued two other companies. The only element arguably missing was the requirement that "sufficient aeration be entrapped to enhance sensitivity to a substantial degree." The appellate court affirmed the declaration of invalidity, finding there was no error in the court's conclusion that "sufficient aeration to enhance sensitivity" was understood by those of ordinary skill in the art to include both interstitial and porous air, or in its determination that the evidence clearly and convincingly established it was inherent in the two anticipating prior art references.

OUTCOME: Finding of invalidity affirmed, because district court correctly interpreted the claims and applied the law of anticipation. Nor was there clear error in factual determination that prior art inherently possessed sufficient aeration to enhance sensitivity to substantial degree within the overlapping ranges. Finding of non-infringement was not addressed.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Infringement > Claim Interpretation
[HN1] The appellate court reviews claim construction in patent contests as a matter of law.

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous ReviewPatent Law > Infringement > Claim Interpretation
[HN2] In patent contests, anticipation is a question of fact, including whether or not an element is inherent in the prior art. The appellate court reviews a finding of anticipation under the clearly erroneous standard.

Patent Law > Novelty & AnticipationPatent Law > Infringement > Claim Interpretation
[HN3] To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. Anticipation of a patent claim requires a finding that the claim at issue "reads on" a prior art reference.

Patent Law > Novelty & Anticipation
[HN4] When a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates

the claim. It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is "anticipated" if one of them is in the prior art. In chemical compounds, a single prior art species within the patent's claimed genus reads on the generic claim and anticipates.

Patent Law > Infringement > Claim Interpretation
[HN5] The focus in construing disputed terms in patent claim language is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean.

Patent Law > Infringement > Claim Interpretation
[HN6] To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art.

Patent Law > Infringement > Claim Interpretation
[HN7] Artisans of ordinary skill may not recognize the inherent characteristics or functioning of prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.

COUNSEL: Stanford B. Owen, Fabian & Clendenin, of Salt Lake City, Utah, argued for plaintiff-appellant, Hanex Products, Inc. With him on the brief were W. Cullen Battle,. Robert A. Garda, Jr., and Jon C. Martinson.

Gordon L. Roberts, Parsons Behle & Latimer, of Salt Lake City, Utah, argued for defendant-appellee, IRECO Incorporated and ICI Explosives USA, Inc. Of counsel on the brief was C. Kevin Speirs.

JUDGES: Before MAYER, Chief Judge, MICHEL and RADER, Circuit Judges.

OPINIONBY: RADER

OPINION: [*1343] RADER, Circuit Judge.

The United States District Court for the District of Wyoming determined that U.S. Patent No. *4,111,727* (the Clay patent) and its reissue, U.S. Patent No. RE *33,788* (the reissue patent) were invalid. Atlas Powder Company (Atlas), a licensee under those patents, sued IRECO Incorporated (IRECO) for infringement of the Clay patent. Following two bench trials, the district court concluded that both the original Clay patent and the reissue patent were invalid as anticipated by either U.S. Patent No. *3,161,551* (Egly) or U.K. Patent No. 1,306,546 (Butterworth). Because [**2] the district court correctly interpreted the claims and applied the law of anticipation, this court affirms the finding of invalidity.

I.

The Clay patent and its reissue both claim explosive compositions. To detonate, [*1344] explosives require both fuel and oxidizers. The oxidizer rapidly reacts with the fuel to produce expanding gases and heat - an explosion. Composite explosives mix various sources of fuel and oxygen. The most widely used and economical composite explosive is ammonium nitrate and fuel oil (ANFO). ANFO explosives mix about 94% by weight of ammonium nitrate (AN), the oxidizer, with 6% by weight of fuel oil (FO). The AN may include porous prills, dense prills, Stengel flakes, or crystalline AN. ANFO explosives have two primary disadvantages. First, wet conditions dissolve the AN and make the explosive unusable in damp settings. Second, ANFO is a relatively weak explosive because interstitial air occupies considerable space in the mixture, thereby decreasing the amount of explosive material per unit of volume.

To address these shortcomings, explosive experts developed water-in-oil emulsions. These emulsions dissolved the oxidizer into water and then dispersed the solution [**3] in oil. Because oil surrounds the oxidizer, it is resistant to moisture, thus solving one of the problems with ANFO. Emulsions also increased the explosive's bulk strength by increasing the density of explosive material in the mixture. Emulsions, however, also have a disadvantage. Emulsions will not detonate unless sensitized. Sensitivity of a blasting composition refers to the ease of igniting its explosion. Experts generally sensitize emulsions by using gassing agents or adding microballoons throughout the mixture. The gassing agents or microballoons provide tiny gas or air bubbles throughout the mixture. Upon detonation, the gas pockets compress and heat up, thereby igniting the fuel around them. In other words, the tiny gas or air bubbles act as "hot spots" to propagate the explosion.

The Clay patent and its reissue both claim composite explosives made from the combination of an ANFO blasting composition and an unsensitized water-in-oil emulsion. Both patents claim essentially the same blasting composition. Claim one of the reissue patent recites:

> 1. A blasting composition consisting essentially of 10 to 40% by weight of a greasy water-in-oil emulsion and 60 to 90% of [**4] a substantially undissolved particulate solid oxidizer salt constituent, wherein the emulsion comprises about 3 to 15% by weight of water, about 2 to 15% of oil, 70 to 90% of powerful oxidizer salt comprising ammonium nitrate which may include other powerful oxidizer salts, wherein the solid constituent comprises ammonium nitrate and in which sufficient aeration is entrapped to enhance sensitivity to a substantial degree, and wherein the emulsion component is emulsified by inclusion of 0.1 to 5% by weight, based on the total composition, of an [oil-in-water] water-in-oil emulsifier to hold the aqueous content in the disperse or internal phase.

(Underline added.)

When this lawsuit began, Atlas was the exclusive licensee under the Clay patent in the continental U.S. and Hawaii. Atlas commenced this lawsuit against IRECO in 1986, alleging infringement of the Clay patent. During the course of litigation, Dr. Robert Clay, the inventor, filed a reissue petition with the United States Patent and Trademark Office (PTO). Atlas then moved to stay the litigation pending resolution of the reissue application. The district court denied that motion and conducted a first bench trial [**5] on the issues of validity and infringement of the Clay patent in October 1986. Dr. Clay then requested suspension of prosecution of the reissue application by the PTO in February 1987. After waiting several years for a decision from the district court, Dr. Clay requested that the PTO reinstate the reissue proceedings in 1990. In January 1992, the Clay reissue patent issued upon surrender of the original patent. Later that [*1345] year, the district court rendered its findings and judgment regarding the validity and infringement of the Clay patent.

In its 1992 judgment, the district court found claims 1, 2, 3, 10, 12, 13, and 14 of the Clay patent invalid as anticipated by either one of two prior art references, Egly or Butterworth. Egly and Butterworth each disclose blasting compositions containing a water-in-oil emulsion and ANFO with ingredients identical to those of the Clay patents in overlapping amounts. The following chart illustrates the overlap between the explosive compositions disclosed in the prior art patents and the Clay reissue patent:

	Clay	Egly	Butterworth
Composition contents:			
Water-in-oil Emulsion	10-40%	20-67%	30-50%
Solid Ammonium Nitrate	60-90%	33-80%	50-70%
Emulsion contents:			
Ammonium Nitrate	70-90%	50-70%	65-85%
Water	about 3-15%	about 15-about 35%	2-27%
Fuel Oil	about 2-15%	about 5-about 30%	2-27%
Emulsifier	0.1-5%	about 1-5%	0.5-15%

The only element of the Clay patent claims which is arguably not present in the prior art compositions is "sufficient [**6] aeration . . . entrapped to enhance sensitivity to a substantial degree." The trial court determined that "sufficient aeration" was an inherent element in the prior art blasting compositions within the overlapping ranges. The district court also found that none of the accused products infringed any of the asserted claims. The 1992 judgment was not final, however, and specifically reserved a decision on the effect of the reissue patent for phase two of the case.

On September 22, 1993, the district court granted Hanex Products Inc.'s (Hanex) motion to intervene in the lawsuit. Hanex owns the two patents and had licensed them to Atlas. Hanex asserted the same claim of patent infringement against IRECO that Atlas had asserted, but also initiated a declaratory judgment action against ICI Explosives USA, Inc. (ICI), Atlas' successor-in-interest, seeking the sole right to control the litigation. In July 1994, the district court granted declaratory relief in favor of Hanex, against ICI, giving Hanex the sole right to control and direct the litigation on the two patents.

After the reissue patent issued, the district court conducted a second bench trial, in January 1996, on the issues of phase [**7] two. Specifically, the district court considered whether reissue affected its 1992 judgment. On September 25, 1998, the district court rendered its final judgment finding claims 1, 2, 3, 10, 12, 13, and 14 of the Clay reissue patent invalid as anticipated and finding that IRECO had not infringed any of the asserted claims. Despite the PTO's consideration of the Egly and Butterworth references during prosecution of the reissue, the district court concluded that IRECO had overcome the Clay reissue patent's presumption of validity under *35 U.S.C. § 282* (1994) by clear and convincing evidence. The district court noted that IRECO presented a great deal of testimonial and documentary evidence on inherent disclosures of the prior art that was not before the PTO in the [*1346] reissue proceeding. Hanex appealed to this court from the 1998 final judgment.

II.

[HN1] This court reviews claim construction as a matter of law. See *Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1451, 46 U.S.P.Q.2D (BNA) 1169, 1173 (Fed. Cir. 1998)* (en banc); *Markman v. Westview Instruments, Inc., 52 F.3d 967, 979, 34 U.S.P.Q.2D (BNA) 1321, 1326 (Fed. Cir. 1995)* (en banc). [HN2] Anticipation is [**8] a question of fact, including whether or not an element is inherent in the prior art. See *In re Schreiber, 128 F.3d 1473, 1477, 44 U.S.P.Q.2D (BNA) 1429, 1431 (Fed. Cir. 1997)*. Therefore, this court reviews a finding of anticipation under the clearly erroneous standard. See *Gechter v. Davidson, 116 F.3d 1454, 1457, 43 U.S.P.Q.2D (BNA) 1030, 1032 (Fed. Cir. 1997)*.

[HN3] "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber, 128 F.3d at 1477*. Anticipation of a patent claim requires a finding that the claim at issue "reads on" a prior art reference. See *Titanium Metals Corp. v. Banner, 778 F.2d 775, 781, 227 U.S.P.Q. (BNA) 773, 778 (Fed. Cir. 1985)*. In other words, if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art. See *id. at 781*. Specifically, [HN4] when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls [**9] within each of the ranges anticipates the claim. See *id. at 780-82* ("It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art."). In chemical compounds, a single prior art species within the patent's claimed genus reads on the generic claim and anticipates. See *In re Gosteli, 872 F.2d 1008, 1010, 10 U.S.P.Q.2D (BNA) 1614, 1616 (Fed. Cir. 1989)*.

As noted previously, both Egly and Butterworth disclose blasting compositions with ingredients identical to those of the Clay patent and its reissue in overlapping amounts. The only element which is arguably missing from the prior art is the requirement that "sufficient aeration [be] entrapped to enhance sensitivity to a substantial degree." To decide the issue of anticipation, therefore, the district court examined whether "sufficient aeration . . . to enhance sensitivity" was inherently part of the prior art compositions. That decision, in turn, required the trial court to interpret the claim term "sufficient aeration." By looking at the express language of the claims and [**10] the patent's written description, the district court concluded that the claim term "sufficient aeration" included both interstitial air (between oxidizer particles) and porous air (within the pores of oxidizer particles).

The first task of this court on appeal is to construe independently the disputed claim term. This question requires this court to determine whether the claim term "sufficient aeration" includes porous air, as the trial court determined. The claim term "sufficient aeration" does not limit the air content of the composition to interstitial air. Rather, the broad term "aeration" contains no qualitative limits on the kind of air exposure, only the quantitative limit that the air exposure be "sufficient" to enhance sensitivity. If the inventor intended "sufficient aeration" to carry qualitative limits, he also did not express that

intention in the patent's written description. The specification gives no explicit definition of the phrase "sufficient aeration . . . to enhance sensitivity," which appears in the patent for the first time in the claims.

[*1347] It is, of course, possible that the inventor did not include qualitative limits on the term "sufficient aeration" in the [**11] specification because those of ordinary skill in the art understand that only interstitial air enhances sensitivity and satisfies the claim's language. See *Autogiro Co. of Am. v. U.S., 181 Ct. Cl. 55, 384 F.2d 391, 397, 155 U.S.P.Q. (BNA) 697 (Ct. Cl. 1967)* ("Claims cannot be clear and unambiguous on their face."); *Markman, 52 F.3d at 986* [HN5] ("The focus in construing disputed terms in claim language is . . . on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."). The trial record, however, shows that those of ordinary skill in this art at the time the patent application was filed knew that both interstitial and porous air enhance sensitivity. Dr. Clay himself, the inventor of the patents in suit, testified that air from any source would contribute to the explosion of a heavy ANFO composition and, particularly, air trapped within the pores of porous prilled AN. Therefore, this court detects no error in the district court's conclusion that "sufficient aeration . . . to enhance sensitivity" is understood by those of ordinary skill in the art to include both interstitial and porous air. [**12] The district court appropriately construed the claims at issue to include aeration from both sources.

III.

Based on its correct interpretation of "sufficient aeration," the district court heard evidence on whether both interstitial and porous air were present and enhanced sensitivity in the prior art explosive compositions. Based on the evidence, the district court concluded that IRECO had shown the inherency of the disputed claim element in the prior art and overcome "the presumption of validity under *35 U.S.C. § 282* by providing clear and convincing evidence of invalidity." This court must determine whether the district court committed clear error by determining that the evidence clearly and convincingly established that "sufficient aeration . . . to enhance sensitivity" was inherent in either Egly or Butterworth.

[HN6] To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See *Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369, 21 U.S.P.Q.2D (BNA) 1321, 1328 (Fed. Cir. 1991).* However, a prior art reference may anticipate when the claim limitation or limitations [**13] not expressly found in that reference are nonetheless inherent in it. See id.; *Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 U.S.P.Q.2D (BNA) 1051, 1053 (Fed. Cir. 1987).* Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re King, 801 F.2d 1324, 1326, 231 U.S.P.Q. (BNA) 136, 138 (Fed. Cir. 1986).* Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See *Titanium Metals, 778 F.2d at 780.* [HN7] Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id. at 782.* However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *id. at 782* ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . ., by one who has discovered its . . . useful properties."); *Verdegaal Bros., 814 F.2d at 633.* [**14]

This court's decision in Titanium Metals illustrates these principles. See *Titanium Metals, 778 F.2d at 775.* In Titanium Metals, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and [*1348] titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." *Titanium Metals, 778 F.2d at 776.* A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." *Id. at 782.* This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or [**15] not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.

The trial record contains exhaustive evidence regarding the inherency of both interstitial and porous air in the Egly and Butterworth compositions within the overlapping ranges. The testimony from expert witnesses for both parties established that whether sufficient air is present in the explosive composition to facilitate detonation is a function of the ratio of the emulsion to the solid constituent. Dr. Clay testified that "if you mix porous prills, for example, with 30% typical water-in-oil emulsions, you're going to have air in there and it will

detonate." Another of Atlas' experts testified that a mixture of 30% of either an Egly or a Butterworth emulsion, mixed with 70% standard fertilizer grade porous AN would have interstitial air, assuming nothing was done to disturb the size distribution of the AN prills. The other experts agreed that the emulsions described in both Egly and Butterworth would inevitably and inherently have interstitial air remaining in the mixture up [**16] to a ratio of approximately 40% emulsion to 60% solid constituent. The expert testimony supports the district court's conclusion that "sufficient aeration" is inherent in both Egly and Butterworth.

The district court also relied on evidence from several tests which showed that "sufficient aeration . . . to enhance sensitivity" was inherently present within the overlapping ranges of the Clay patents and Egly and Butterworth. In tests conducted with porous prilled AN combined with FO, stable detonations were obtained in every 8" diameter bore hole test where the percentage of emulsion ranged from 30% to 42.5%. Butterworth specifically discloses the use of porous prilled AN. Butterworth, p. 3, ll. 35-50. These tests, therefore, support the finding that "the emulsions described by Butterworth, combined with the ratios of ANFO disclosed by Butterworth, would inevitably and inherently have interstitial air remaining up to approximately 40% emulsion." The district court also found that the solid AN disclosed in Egly would have included porous prills. These tests, therefore, further support the court's finding that "emulsions described in the Egly Patent, combined with either AN or ANFO, [**17] would inevitably and inherently have interstitial air remaining in the mixture up to approximately 40% emulsion to 60% solid constituent." This court discerns no clear error in the district court's conclusion that "sufficient aeration" was inherent in each anticipating prior art reference.

Because "sufficient aeration" was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of Dr. Clay's alleged invention - that air may act as the sole sensitizer of the explosive composition. An inherent structure, composition, or function is not [*1349] necessarily known. See, e.g., *In re King, 801 F.2d at 1327; Titanium Metals, 778 F.2d at 782.* Once it is recognized that interstitial and porous air were inherent elements of the prior art compositions, the assertion that air may act as a sole sensitizer amounts to no more than a claim to the discovery of an inherent property of the prior art, not the addition of a novel element. Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation. See *Titanium Metals, 778 F.2d at 782.* In addition, there [**18] was evidence that Butterworth did recognize the functioning of interstitial and porous air in sensitizing the composition. Butterworth recognizes the need for a gaseous sensitizer. Butterworth, p. 2, ll. 38-56. It teaches that the "sensitizer may be a gaseous sensitizer present in the composition in the form of gas bubbles or discrete particles containing an entrapped gas such as air." Id., p. 2, ll. 41-45. Although this typically suggests use of a gassing agent or microballoons, Butterworth expressly recognizes that in certain ranges (i.e., 50% to 70% by weight of ANFO) the mixture of porous prilled AN and FO alone provides the necessary sensitization. See id., p. 3, ll. 37-50. The district court found that Butterworth thus inherently appreciates that interstitial and porous air may serve as the necessary sensitizer. This court discerns no clear error in that finding.

In reaching this judgment, this court notes that Egly teaches away from air entrapment. Specifically, Egly teaches that it is desirable to "fill all spaces in between each particle to give added density." Egly, col. 1, ll. 26-27. This statement in Egly, however, does not defeat the district court's finding of [**19] anticipation for several reasons. First, Egly's teaching does not in any way discredit the trial court's alternative reliance on Butterworth for invalidation of the Clay patent and its reissue. More important, the statement in Egly is, in fact, only a showing that Egly did not recognize the function of the inherently present interstitial air. As noted previously, an insufficient scientific understanding does not defeat a showing of inherency. In fact, even in Egly itself, the only way taught for removing interstitial air is the addition of more emulsion. See id., col. 1, ll. 50-55. Egly, however, teaches the use of a broad range - between 20% and 67% by weight - of water-in-oil emulsion. See id., col. 3, ll. 21-24. While Egly compositions containing amounts approaching 67% by weight of water-in-oil emulsions may have little or no entrapped air, the evidence established that at emulsion levels below 40%, Egly compositions "inevitably and inherently" trap sufficient amounts of air to enhance sensitivity. This evidence included both substantial amounts of expert testimony and data showing extensive testing of Egly compositions.

Finally, although the record showed that special [**20] mixing techniques - such as grinding and screening the AN particles - remove interstitial air from the blasting compositions, Egly did not teach or suggest any such techniques. Thus, although Egly may have suggested removal of air, it nonetheless inherently contained interstitial aeration sufficient to enhance sensitivity when comprised of elements within the Clay patent ranges. Consequently, this court discerns no clear error in the district court's conclusion that Egly compositions within the range of the Clay patent claims inherently contain sufficient air to enhance sensitivity.

Based upon all the evidence, substantial amounts of which were not before the PTO in its reissue examination, the district court concluded that IRECO had proven

> clearly and convincingly that, unless extraordinary measures are taken to grind and screen ammonium nitrate, the existence of "interstitial air," or sufficient [*1350] aeration to sustain a stable detonation, is a function of the ratios of emulsion to solid constituent. Specifically, at ratios of 30% emulsion and 70% solid constituent, which are common to the Clay Patent, the Egly Patent, and the Butterworth Patent, there is inherently sufficient [**21] aeration to sustain a stable detonation, barring extraordinary efforts to grind and screen the ammonium nitrate used in the solid constituent.

This court discerns no clear error in the district court's factual determination that the prior art inherently possesses sufficient aeration to enhance sensitivity to a substantial degree within the overlapping ranges. Nor does this court discern clear error in the district court's finding of anticipation based on either Egly or Butterworth. To uphold the Clay patent and its reissue would preclude the public from practicing the prior art.

III.

In conclusion, this court affirms the district court's finding of invalidity with respect to claims 1, 2, 3, 10, 12, 13, and 14 of the Clay patent and the Clay reissue patent. This court therefore does not address the district court's additional finding of non-infringement.

COSTS

Each party shall bear its own costs.

AFFIRMED.

LEXSEE

IN RE SCHREIBER

97-1201

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

128 F.3d 1473; 1997 U.S. App. LEXIS 29099; 44 U.S.P.Q.2D (BNA) 1429

October 23, 1997, Decided

SUBSEQUENT HISTORY: [**1] Suggestion for Rehearing In Banc Declined and Rehearing Denied December 17, 1997, Reported at: *1997 U.S. App. LEXIS 37546.*

PRIOR HISTORY: Appealed from: Patent and Trademark Office Board of Patent Appeals and Interferences. (Serial No. 08/187,111).

DISPOSITION: AFFIRMED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant patent applicant claimed patents on a device for dispensing popcorn. The Patent Office denied four of the patent claims. Appellee Patent and Trademark Office Board of Patent Appeals and Interferences (board) upheld the rejections. The patent applicant sought review of the board's decision.

OVERVIEW: The patent applicant filed patent claims for a device that was conical shaped with a large opening that fit on a container and a smaller opening at the opposite end that allowed the popped popcorn to pass though a few kernels at a time when the device was attached to a popcorn container. The board found that a prior patent that disclosed a spout for nozzle-ready canisters anticipated some of the patent claims. The board also found that some of the patent claims were obvious to one of ordinary skill in the art. On appeal, the court ruled that the patent claims were inherent and anticipated by the prior patent. The court held that the recitation of a new intended use for the old product did not make claims to that old product patentable. The court also held that the board did not err in its determination that the patent claims were obvious.

OUTCOME: The court affirmed the order from the board that sustained a final rejection of the patent applicant's claims.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Novelty & Anticipation
[HN1] To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. Anticipation is an issue of fact, and the question whether a claim limitation is inherent in a prior art reference is a factual issue on which evidence may be introduced.

Patent Law > Novelty & Anticipation
[HN2] The recitation of a new intended use for an old product does not make a claim to that old product patentable. The discovery of a new property or use of a previously known composition, even when that property and use are not obvious from prior art, can not impart patentability to claims to the known composition.

Patent Law > Novelty & Anticipation
[HN3] The question whether a reference is analogous art is irrelevant to whether that reference anticipates. A reference may be from an entirely different field of endeavor than that of the claimed invention or may be directed to an entirely different problem from the one addressed by the inventor, yet the reference will still anticipate if it explicitly or inherently discloses every limitation recited in the claims.

Patent Law > Novelty & AnticipationPatent Law > Specification & Claims > Description Requirement
[HN4] A patent applicant is free to recite features of an apparatus either structurally or functionally. There is nothing intrinsically wrong with defining something by what it does rather than what it is]in drafting patent claims. Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

Evidence > Procedural Considerations > Inferences & PresumptionsPatent Law > Novelty & Anticipation
[HN5] When a prior patient establishes a prima facie case of anticipation the burden shifts to the patient applicant to show that the prior art structure did not inherently possess the functionally defined limitations of his claimed apparatus.

COUNSEL: Joseph B. Taphorn, of Poughkeepsie, New York, argued for appellant.

Joseph G. Piccolo, Associate Solicitor, Office of the Solicitor, Patent and Trademark Office, Department of Commerce, of Arlington, Virginia, argued for the appellee. With him on the brief were Nancy J. Linck, Solicitor, Albin F. Drost, Deputy Solicitor, and Karen A. Buchanan, Associate Solicitor.

JUDGES: Before NEWMAN, PLAGER, and BRYSON, Circuit Judges. Opinion for the court filed by Circuit Judge BRYSON. Dissenting opinion filed by Circuit Judge NEWMAN.

OPINIONBY: BRYSON

OPINION: [*1474] BRYSON, Circuit Judge.

Stephen B. Schreiber appeals the decision of the United States Patent and Trademark Office's Board of Patent Appeals and Interferences sustaining a final rejection of four claims of Schreiber's patent application. We affirm.

I

Schreiber's patent application claims a device for dispensing popped popcorn. The device is conically shaped with a large opening that fits on a container and a smaller opening at the opposite end that allows popped popcorn to pass through when the device is attached [**2] to a popcorn container and turned upside down. An embodiment disclosed in Schreiber's patent application is depicted below. [*1475]

[SEE ILLUSTRATION IN ORIGINAL].

Schreiber filed a number of claims, and the examiner allowed many of the claims. Claims 1, 2, 14, and 15 were finally rejected, however, and those claims are the subjects of this appeal. Claim 1 recites:

> A dispensing top for passing only several kernels of a popped popcorn at a time from an open-ended container filled with popped popcorn, having a generally conical shape and an opening at each end, the opening at the reduced end allows several kernels of popped popcorn to pass through at the same time, and means at the enlarged end of the top to embrace the open end of the container, the taper of the top being uniform and such as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container.

Claim 2 is similar to claim 1 but additionally recites that the top comprises a "means at the reduced end of the top to close-off the opening thereat." The other two claims, claims 14 and 15, depend from claims [**3] 1 and 2, respectively. Schreiber does not argue that claims 14 and 15 are patentable if claims 1 and 2 are not. Accordingly, because we affirm the rejection of claims 1 and 2, we need not address claims 14 and 15.

Claim 1 was rejected by the examiner under *35 U.S.C. § 102*(b) as being anticipated by Swiss Patent No. 172,689 to Harz. The Harz patent discloses "a spout for nozzle-ready canisters," which may be tapered inward in a conical fashion, and it states that the spout is useful for purposes such as dispensing oil from an oil can. The examiner explained that Harz discloses a conical dispensing top for an open-ended container and concluded that "the Harz top is clearly capable of dispensing popped popcorn." Figure 5 from Harz is depicted below. [*1476]

[SEE ILLUSTRATION IN ORIGINAL].

Claim 2 was rejected by the examiner under *35 U.S.C. § 103* as being unpatentable over the combination of Harz and U.S. Patent No. *3,537,623* to Fisher. The examiner stated that although Harz does not disclose a "means at the reduced end of the top to close-off the opening thereat," Fisher does. The examiner concluded that it would have been obvious to one of ordinary skill in the

art to modify [**4] Harz in view of Fisher in order to "seal[ ] the container contents from contaminates."

In response to the patent examiner's rejections, Schreiber submitted a declaration stating that the conical dispensing top depicted in figure 5 of Harz was incapable of "jamming up the popped popcorn before the end of the cone and permitting the dispensing of only a few kernels at a shake of a package when the top is mounted on the container." The examiner did not enter that declaration in the record because he believed it had not been properly submitted. When Schreiber appealed to the Board, the Board remanded the case to the examiner to consider the declaration. On remand, the examiner considered the declaration but found that it did not provide sufficient information to support Schreiber's assertion that a dispensing top built according to Harz does not inherently possess the functionally defined limitations recited in the claims.

Schreiber again appealed to the Board, which upheld the rejections. The Board first found that Harz discloses every limitation recited in claim 1. Several of the recitations in the claims, the Board concluded, merely set forth the function and intended use [**5] of the top and therefore did not require any structural feature other than those taught by Harz. The Board found that the structure disclosed by Harz is inherently capable of dispensing popcorn in the manner set forth in the claims, and that Schreiber's declaration did not provide enough details to prove that the structure disclosed by Harz is incapable of performing the claimed functions of Schreiber's invention.

In response to Schreiber's argument that the conical dispensing top disclosed in Harz is designed to dispense liquids such as oil, rather than solid items such as popcorn, and that it is not large enough to pass popcorn kernels, the Board noted that the Harz patent referred to the use of the claimed device for lubricating oil only as an "example," and found that one of skill in the art "would perceive the top of Harz as being of broader application." The Board further found that the dispensing top disclosed in Harz "is of a relative size and has a taper which would inherently permit popped popcorn kernels to jam up before the end of the cone and permit the dispensing of only a few kernels at a [*1477] shake of the package" when the top is mounted on a popped popcorn container. [**6] Accordingly, the Board concluded that "all the limitations of claim 1 are found in Harz, either expressly or under the principles of inherency, and this claim is clearly anticipated thereby."

As for claim 2, the Board found that Fisher disclosed a means for closing off the smaller end of a conically shaped top and further found that it would have been obvious to one of ordinary skill in the art to provide a close-off mechanism for a top of the sort disclosed by Harz, to prevent dirt and other contaminating matter from entering the opening in the device. Schreiber appeals both of the Board's determinations.

II

Schreiber first argues that Harz does not anticipate claim 1. [HN1] To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. See *Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047, 34 U.S.P.Q.2D (BNA) 1565, 1567 (Fed. Cir. 1995).* Anticipation is an issue of fact, see *In re Graves, 69 F.3d 1147, 1151, 36 U.S.P.Q.2D (BNA) 1697, 1700 (Fed. Cir. 1995); Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677, 7 U.S.P.Q.2D (BNA) 1315, 1317 (Fed. Cir. 1988),* and the question whether a claim limitation is inherent in a [**7] prior art reference is a factual issue on which evidence may be introduced, see *Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991).*

There is no dispute that the structural limitations recited in Schreiber's application are all found in the Harz reference upon which the examiner and the Board relied. Thus, to use the terms found in Schreiber's claim 1, Harz discloses a "dispensing top" that has "a generally conical shape and an opening at each end," and "means at the enlarged end of the top to embrace the open end of the container, the taper of the top being uniform." Schreiber argues, however, that Harz does not disclose that such a structure can be used to dispense popcorn from an open-ended popcorn container.

Although Schreiber is correct that Harz does not address the use of the disclosed structure to dispense popcorn, the absence of a disclosure relating to function does not defeat the Board's finding of anticipation. It is well settled that [HN2] the recitation of a new intended use for an old product does not make a claim to that old product patentable. See *In re Spada, 911 F.2d 705, 708, 15 U.S.P.Q.2D (BNA) 1655, 1657 (Fed.* [**8] *Cir. 1990)* ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition."); *Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782, 227 U.S.P.Q. (BNA) 773, 778 (Fed. Cir. 1985)* (composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); *In re Pearson, 494 F.2d 1399, 1403, 181 U.S.P.Q. (BNA) 641, 644 (CCPA 1974)* (intended use of an old composition does not render

composition claim patentable); *In re Zierden, 56 C.C.P.A. 1223, 411 F.2d 1325, 1328, 162 U.S.P.Q. (BNA) 102, 104 (CCPA 1969)* ("Mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."); *In re Sinex, 50 C.C.P.A. 1004, 309 F.2d 488, 492, 135 U.S.P.Q. (BNA) 302, 305 (CCPA 1962)* (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus); *In re Hack, 44 C.C.P.A. 954, 245 F.2d 246, 248, 114 U.S.P.Q. (BNA) 161, 162 (CCPA 1957)* ("the grant of a patent on a composition or a machine cannot be predicated on a new use of that machine or composition"); *In re Benner, 36 C.C.P.A. 1081, 174 F.2d 938, 942, 82* [**9] *U.S.P.Q. 49, 53 (CCPA 1949)* ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product"). Accordingly, Schreiber's contention that his structure will be used to dispense popcorn does not have patentable weight if the structure is already known, regardless of whether it has ever been used in any way in connection with popcorn.

Schreiber makes the closely related argument that Harz does not anticipate claim 1 because Harz is non-analogous art to which one of ordinary skill in the art would not have looked in addressing the problem of dispensing tops for popped popcorn containers. [*1478] However, [HN3] the question whether a reference is analogous art is irrelevant to whether that reference anticipates. See *In re Self, 671 F.2d 1344, 1350, 213 U.S.P.Q. (BNA) 1, 7 (CCPA 1982).* A reference may be from an entirely different field of endeavor than that of the claimed invention or may be directed to an entirely different problem from the one addressed by the inventor, yet the reference will still anticipate if it explicitly or inherently discloses every limitation recited in the claims.

Schreiber further argues that the functional limitations of his [**10] claim distinguish it from Harz. In particular, Schreiber points to the recitation that the claimed top "allows several kernels of popped popcorn to pass through at the same time," and that the taper of the top is such "as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container."

[HN4] A patent applicant is free to recite features of an apparatus either structurally or functionally. See *In re Swinehart, 58 C.C.P.A. 1027, 439 F.2d 210, 212, 169 U.S.P.Q. (BNA) 226, 228 (CCPA 1971)* ("There is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. As our predecessor court stated in *Swinehart, 439 F.2d at 213, 169 U.S.P.Q. (BNA) at 228:*

> where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter [**11] shown to be in the prior art does not possess the characteristic relied on.

See also *In re Hallman, 655 F.2d 212, 215, 210 U.S.P.Q. (BNA) 609, 611 (CCPA 1981); In re Ludtke, 58 C.C.P.A. 1159, 441 F.2d 660, 663-64, 169 U.S.P.Q. (BNA) 563, 565-67 (CCPA 1971).*

The examiner and the Board both addressed the question whether the functional limitations of Schreiber's claim gave it patentable weight and concluded that they did not, because those limitations were found to be inherent in the Harz prior art reference. To begin with, contrary to the characterization in the dissent, nothing in Schreiber's claim suggests that Schreiber's container is "of a different shape" than Harz's. In fact, as shown above, an embodiment according to Harz (Fig. 5) and the embodiment depicted in figure 1 of Schreiber's application have the same general shape. For that reason, the examiner was justified in concluding that the opening of a conically shaped top as disclosed by Harz is inherently of a size sufficient to "allow[] several kernels of popped popcorn to pass through at the same time" and that the taper of Harz's conically shaped top is inherently of such a shape "as to by itself jam up the popped popcorn before the end [**12] of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container." The examiner therefore correctly found that Harz established a prima facie case of anticipation.

[HN5] At that point, the burden shifted to Schreiber to show that the prior art structure did not inherently possess the functionally defined limitations of his claimed apparatus. See *In re Spada, 911 F.2d at 708, 15 U.S.P.Q.2D (BNA) at 1658; In re King, 801 F.2d 1324, 1327, 231 U.S.P.Q. (BNA) 136, 138-39 (Fed. Cir. 1986); In re Best, 562 F.2d 1252, 1254-55, 195 U.S.P.Q. (BNA) 430, 433 (CCPA 1976).* The Board found that Schreiber failed to do so, and we agree. Schreiber's declaration asserts that he built a conically shaped top according to figure 5 of Harz and that it was too small to jam and dispense popcorn as recited in the claim. The declaration, however, does not specify the dimensions of either the

dispensing top that was tested or the popcorn that was used.

Moreover, the Board found as a factual matter that the top disclosed in figure 5 of the Harz patent "is capable of functioning to dispense kernels of popped popcorn in the manner set forth in claim 1." Starting with Schreiber's [**13] assumption that Harz should be limited to use as an attachment to an oil can, the Board scaled figure 5 to the proportions necessary to fit the Harz container on top of a standard one-quart oil can, as Schreiber suggested in his request for reconsideration. After scaling the Harz figure in that manner, the Board found that the Harz dispenser [*1479] would be capable of dispensing popcorn in the manner set forth in claim 1 of Schreiber's application.

The dissenting opinion incorrectly states that the Board "used Mr. Schreiber's invention as a template" in determining that the Harz dispenser anticipates Schreiber's invention. In fact, the Board simply scaled the dispenser illustrated in Harz figure 5 up to the size necessary to fit a standard oil can, without changing the proportions of the figure in any way. (The top depicted in figure 5 of the Harz patent was obviously not intended to be a full-sized representation of the Harz invention, any more than the top depicted in figure 1 of Schreiber's application was intended to be a full-sized representation of his invention.) The portion of the dissenting opinion addressed to this point is therefore based on a false premise - that the prior [**14] art device was "altered by the Board and then found to anticipate a different invention in whose image it was recreated." The Board's finding that the scaled-up version of figure 5 of Harz would be capable of performing all of the functions recited in Schreiber's claim 1 is a factual finding, which has not been shown to be clearly erroneous. On this ground alone, the Board's anticipation ruling must be upheld.

In any event, however, it is not enough for Schreiber to contend that a top built according to the proportions of figure 5 of Harz is incapable of performing the jamming and dispensing functions. The figures from Harz were provided only as "design examples of the invention"; the disclosure of the Harz patent is thus much broader than the precise conical shape disclosed in figure 5. Moreover, contrary to Schreiber's suggestion, the structure disclosed in Harz is not limited to use as an oil can dispenser. While that use is given as the principal example of the uses to which the invention could be put, nothing in the Harz patent suggests that the invention is in any way limited to that use. In sum, Schreiber's declaration fails to show that Harz inherently lacks the functionally [**15] defined limitations recited in claim 1 of the application. Accordingly, we agree with the Board that Schreiber has failed to rebut the prima facie case of anticipation identified by the examiner. The Board's factual finding on the issue of anticipation is therefore affirmed.

III

Schreiber also challenges the Board's finding that claims 2 and 15 are unpatentable under *35 U.S.C. § 103* as being obvious over the combination of Harz and Fisher. Schreiber argues that the combination of Harz and Fisher does not disclose all the limitations of claim 2 because neither Harz nor Fisher discloses the functionally defined features of the top. That argument is without merit because, as we have already noted, Harz discloses those functionally defined limitations.

Schreiber also argues that Fisher does not provide the function that the "means for closing off" in Schreiber's application provides. The functions Schreiber cites - enabling a person to carry a popped-popcorn package in a non-upright position without spillage, keeping the popcorn warm, and facilitating the mixing of ingredients - are not recited as part of the means-plus-function clause in claim 2. Accordingly, those functions cannot [**16] impart patentability to the claim.

Schreiber further argues that Fisher is non-analogous art because Fisher relates to pouring oil from an oil can whereas Schreiber's invention relates to popcorn dispensing. That argument was not raised before the Board and we therefore decline to consider it for the first time on appeal. Even if we were to consider that argument, however, we note that Schreiber acknowledges in the specification that the prior art pertinent to his invention includes patents relating to dispensing fluids. Schreiber therefore may not now argue that such patents are non-analogous art. See *Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1570, 7 U.S.P.Q.2D (BNA) 1057, 1063 (Fed. Cir. 1988); In re Fout, 675 F.2d 297, 300, 213 U.S.P.Q. (BNA) 532, 535 (CCPA 1980); In re Wood, 599 F.2d 1032, 1036, 202 U.S.P.Q. (BNA) 171, 174 (CCPA 1979); In re Nomiya, 509 F.2d 566, 571, 184 U.S.P.Q. (BNA) 607, 611-12 (CCPA 1975).* Accordingly, we find no error in the Board's [*1480] determination that claims 2 and 15 would have been obvious.

AFFIRMED.

DISSENTBY: NEWMAN

DISSENT: NEWMAN, Circuit Judge, dissenting.

I respectfully dissent. The panel majority affirms the PTO position that the express limitations [**17] of the claims are irrelevant when dealing with a rejection on the

ground of "anticipation." The court thus departs from the rules of claim interpretation on which we have placed so much weight. The Federal Circuit has held, over and over, that every claim limitation is important and none can be ignored -- and now proceeds to ignore several express limitations. Thus the panel incongruously holds that a claim that requires, explicitly and precisely, a container of popcorn and a dispenser that passes only a few kernels of popcorn before jamming, is "anticipated" by an oil can of a different shape as illustrated in a reference that neither shows nor suggests a container filled with popcorn or the jamming of the dispenser upon dispensing the popcorn. I feel for those who tread the arcane path of patent soliciting, for this court's insistence on the importance of the limitations in the claims seems to have lost its way.

Schreiber's claims 1 and 14 are representative:

> 1. A dispensing top for passing only several kernels of a popped popcorn at a time from an open-ended container filled with popped popcorn, having a generally conical shape and an opening at each end, the opening at the [**18] reduced end allows several kernels of popped popcorn to pass through at the same time, and means at the enlarged end of the top to embrace the open end of the container, the taper of the top being uniform and such as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container.
>
> 14. A package consisting of a container having popped popcorn and having an open end and embracing thereat a dispensing top according to claim 1.

The Board held that it is irrelevant that the Schreiber claims are limited to a container filled with popped popcorn with the additional limitation of dispensing a few kernels at a time before the dispenser jams up. No popcorn container or dispenser was cited by the PTO, and no similar claim limitations were cited by the PTO. These claim limitations can not be ignored. See *Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1532, 3 U.S.P.Q.2D (BNA) 1321, 1324 (Fed. Cir. 1987)* (the court can not ignore a plethora of meaningful limitations). Patentability is determined for the invention as claimed, with all its limitations. It is improper to [**19] delete explicit limitations from the claim in order to find the residue in the prior art.

"That which infringes if later anticipates if earlier." *Polaroid Corp. v. Eastman Kodak Co., 789 F.2d 1556, 1573, 229 U.S.P.Q. (BNA) 561, 574 (Fed. Cir. 1986)* (citing *Peters v. Active Mfg. Co., 129 U.S. 530, 537, 32 L. Ed. 738, 9 S. Ct. 389 (1889))*. It is inconceivable that this or any court would find Mr. Schreiber's claims to this popcorn dispenser infringed by the oil can of the Harz reference. The claim limitations that the container is filled with popped popcorn and that only a few kernels of popcorn are released at a time could not be ignored in an infringement action, and they are not properly ignored in a patentability action.

The Board, using Mr. Schreiber's invention as a template, rescaled the prior art and filled the oil can with popcorn. This exercise of hindsight is not "anticipation." The law of anticipation requires that the same invention, with all the limitations of the claims, existed in the prior art. See *Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2D (BNA) 1913, 1920-21 (Fed. Cir. 1989)* ("anticipation" requires that the identical invention is described in a single prior art reference). A [**20] prior art device can not be altered by the Board and then found to anticipate a different invention in whose image it was recreated.

In responding to the PTO's rejection, Mr. Schreiber made an actual conical top according to the Harz oil can's proportions, and reported that the popcorn did not behave as in his device. The Board then proposed that [*1481] Mr. Schreiber had erred in determining the diameter of the opening, and postulated that with the appropriate opening the Harz oil can might behave as does Mr. Schreiber's container. Mr. Schreiber says this is incorrect. I say it is irrelevant. See, e.g., *Richardson, 868 F.2d at 1236, 9 U.S.P.Q.2D (BNA) at 1920* (every element of the claim must be shown in the reference, including all limitations); *In re Paulsen, 30 F.3d 1475* (the reference must describe the claimed invention sufficiently to place it in the possession of a person of ordinary skill in the field).

Mr. Schreiber's popcorn dispenser is not described in the prior art. Statements in the claims that define and limit the device are material limitations, for purposes of infringement and for purposes of distinguishing from the prior art. See, e.g., *Rowe v. Dror, 112* [**21] *F.3d 473, 478-79, 42 U.S.P.Q.2D (BNA) 1550, 1553-54 (Fed. Cir. 1997)* (the field of the invention as stated in a Jepson-type claim limits the invention); *Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677-78, 7 U.S.P.Q.2D (BNA) 1315, 1317 (Fed. Cir. 1988)* (limitations stated in the preamble limit the claimed invention); *In re Stencel, 828 F.2d 751, 754-55, 4 U.S.P.Q.2D (BNA) 1071, 1073 (Fed. Cir. 1987)* (function stated in claim distinguishes from prior art). The rejection for lack of novelty is simply incorrect.

In *Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 137 L. Ed. 2d 146, 117 S. Ct. 1040 (1997)* the Court stressed the importance of claim limitations. The cases cited by the panel majority relate to the discovery of a new use of a known composition or device, and hold that the discovery of that use does not render patentable that which is already known. However, Schreiber's device is not known, but is new, and the claims are explicitly so limited. See *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1255-57, 9 U.S.P.Q.2D (BNA) 1962, 1965-66 (Fed. Cir. 1989)* ("To read the claim in light of the specification indiscriminately to cover all types of optical fibers would be divorced from reality."); [**22] *W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540* or *842 F.2d 1275* (anticipation can not be based on conjecture). The claimed popcorn dispenser having a novel structure and function, whereby the container is filled with popcorn and after a few kernels of popcorn are released the dispenser jams up, is not in the cited prior art. The explicit claim limitations must be considered in determination of anticipation, just as they would be considered in construing the claims for the purpose of determining infringement. They can not be ignored.

Since no prior art shows this device, it can not be "anticipated" as lacking novelty.

B

The panel majority suggests that it would be "inherent" to use the oil can as a popcorn dispenser. An inherent disclosure, to be invalidating as an "anticipation," is a disclosure that is necessarily contained in the prior art, and would be so recognized by a person of ordinary skill in that art. *Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268-69, 20 U.S.P.Q.2D (BNA) 1746, 1749-50 (Fed. Cir. 1991).* "Inherency" charges the inventor with knowledge that would be known to the art, although not described. Inherency is not a matter of hindsight [**23] based on the applicant's disclosure: the missing claim elements must necessarily be present in the prior art.

The authority cited by the majority, relating to claiming a known composition or device based on discovery of a new use, is inapt. It is of course correct that the discovery of a new use of a known composition or device does not render that composition or device patentable per se. The reason, however, is not "inherency"; it is that the composition or device is already known to the public, and can not be removed from the public. (The new use can of course be claimed as a method of use.) In this case, however, Mr. Schreiber has created a new device, not previously known to the public, and has claimed his new device with explicit limitations that distinguish it from previously known devices.

In passing, I also observe that the majority errs in stating that advantages not recited in the claim can not impart patentability to a new device. The advantages of an invention are often relied on to support patentability; whether they are included in the claim depends on a variety of factors, and is not the subject of a rigid rule.

[*1482] The issue in this case is anticipation; that is, novelty. [**24] Since the claimed invention is not described in a single prior art reference, it is not "anticipated."

LEXSEE

SCHERING CORPORATION, Plaintiff, v. PRECISION-COSMET CO., INC., Defendant

Civil Action No. 83-829-WKS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

614 F. Supp. 1368; 1985 U.S. Dist. LEXIS 18262; 227 U.S.P.Q. (BNA) 278

July 2, 1985

CASE SUMMARY:

PROCEDURAL POSTURE: This patent infringement matter came before the court on the following post-trial motions: defendant's motion for judgment notwithstanding the verdict and, in the alternative, for a new trial; and plaintiff's motion for an award of prejudgment interest, increased damages, and reasonable attorney's fees.

OVERVIEW: In a patent infringement action, the jury returned a general verdict for plaintiff along with answers to interrogatories, including a finding that defendant's infringement was willful. This matter came before the court on the following post-trial motions: defendant's motion for judgment notwithstanding the verdict and, in the alternative, for a new trial; and plaintiff's motion for an award of prejudgment interest, pursuant to *35 U.S.C.S. § 284;* increased damages, pursuant to *35 U.S.C.S. § 284;* and reasonable attorney's fees, pursuant to *35 U.S.C.S. § 285.* Court denied defendant's motion for judgment notwithstanding the verdict or a new trial. Court granted plaintiff's motion, awarding plaintiff double the damages found by the jury, interest from the time each reasonable royalty payment would have been made until the date of judgment, and attorney's fees in an amount to be agreed upon or determined by the court.

OUTCOME: Court denied defendant's motion for judgment notwithstanding verdict or new trial. Court granted plaintiff's motion, awarding plaintiff double damages found by jury, interest from time each reasonable royalty payment would have been made until date of judgment, and attorney's fees in amount to be agreed upon or determined by court.

LexisNexis (TM) HEADNOTES - Core Concepts:

Civil Procedure > Trials > Judgment as Matter of Law
[HN1] The moving party is entitled to a judgment notwithstanding the verdict (JNOV) when the court is convinced: (1) that reasonable persons could not in light of the evidence have found the facts necessary to support the jury's verdict; or (2) that the facts properly found cannot in law support that verdict. If, on the other hand, the court is convinced that reasonable persons could have found in light of the evidence the facts necessary to support in law the jury's verdict, denial of the motion for JNOV is required.

Civil Procedure > Trials > Judgment as Matter of Law
[HN2] The Federal Circuit has set forth guidelines that a court must follow in considering a motion for judgment notwithstanding the verdict. Under these guidelines, a court must: (1) consider all the evidence; (2) in a light most favorable to the non-mover; (3) drawing reasonable inferences favorable to the non-mover; (4) without determining credibility of witnesses; and (5) without substituting its choice for that of the jury between conflicting elements in the evidence.

Civil Procedure > Trials > Judgment as Matter of LawPatent Law > Infringement > Defenses
[HN3] Where the issue raised is validity, the true question is whether defendant, which bore the burden, *35 U.S.C.S. § 282,* submitted such evidence as would preclude a reasonable jury from reaching a verdict of validity. In this regard, it is well to note that the question

presented by a motion for judgment notwithstanding the verdict is not whether the district court would have found the invention obvious as though there had been no trial before a jury. Rather, the question is whether the jury's verdict that the patent is valid (i.e. has not been proved invalid) is supported by substantial evidence.

Patent Law > Nonobviousness > Tests & Proof of ObviousnessCivil Procedure > Jury Trials > Province of Court & Jury
[HN4] Though obviousness is a question of law, it is an issue that may properly be submitted to a jury, in the same manner that other legal questions, such as negligence, are regularly submitted to juries in personal injury cases.

Civil Procedure > Jury Trials > Province of Court & Jury
[HN5] The jury is entitled to reject a witness's testimony if they do not find it credible. And it is not the province of the court to weigh the credibility of a witness's testimony against the testimonies of other witnesses.

Patent Law > Novelty & AnticipationPatent Law > Infringement > Burdens of Proof
[HN6] A party asserting that a patent claim is anticipated under *35 U.S.C.S. § 102* must demonstrate identity of invention. Identity of invention is a question of fact, and one who seeks such a finding must show that each element of the claim in issue is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice.

Patent Law > Novelty & Anticipation
[HN7] The general rule is that a prior genus does not anticipate a later species. If, however, it is possible to derive a class of compounds of lesser scope than the genus disclosed in a prior art reference on the basis of preferences ascertainable from the remainder of the reference, anticipation may be found. The anticipating reference must contain within its four corners a sufficient description to enable one to practice the invention without experimentation or inventive skill. The test is whether the prior art reference describes the invention with sufficient clarity and specificity so that one skilled in the art may practice the invention without assistance from the patent claimed to have been anticipated.

Patent Law > Novelty & Anticipation
[HN8] A new use for an old substance is not patentable.

Patent Law > Novelty & Anticipation
[HN9] The rule that no product patent may issue for discovery of a new use for an old product or process is tempered by the doctrine of slight changes. The doctrine of slight changes extends to the area of chemical compounds. The modification of an old compound into a new patentable one may be slight.

Patent Law > Novelty & Anticipation
[HN10] A mere change in the amount of a compound has been deemed sufficient to change an old composition into a new one.

Patent Law > Specification & Claims > Claim Preambles
[HN11] The Court of Claims and Patent Appeals set down guidelines for determining when the introductory phrase of a claim would be permitted to limit the claim itself. The court indicated that the preamble would be permitted to limit a claim where it was deemed essential to point out the invention defined by the claim or count, that is, where the preamble was considered necessary to give life, meaning, and vitality to the claims or counts.

Patent Law > Specification & Claims > Claim Preambles
[HN12] The Court of Appeals for the Federal Circuit has looked to the preamble when necessary to give meaning to the claim and properly define the invention.

Patent Law > Infringement > Claim Interpretation
[HN13] Claims should be so construed, if possible, as to sustain their validity.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN14] While it is true that close structural similarity between prior art compounds and those that are claimed may be an indicia of obviousness, the subject matter of the invention as a whole may be non-obvious if the claimed compound has unexpected properties.

Civil Procedure > Trials > Judgment as Matter of LawCivil Procedure > Relief From Judgment > Motions for New Trial
[HN15] A motion for a new trial differs from a motion for judgment notwithstanding the verdict in that a motion for a directed verdict or for judgment notwithstanding the verdict raises the legal sufficiency of the evidence, and is to be sharply distinguished from a motion for a new trial on the ground that the verdict is against the weight of the evidence. The latter motion is addressed to the sound discretion of the trial court, which may set aside the verdict as contrary to the preponderance of the evidence although a directed verdict or judgment notwithstanding the verdict is not justified.

Civil Procedure > Relief From Judgment > Motions for New Trial
[HN16] The standard of review in considering a motion for a new trial is most often formulated in one of three ways. Thus, a new trial will be granted if the verdict is against the clear weight of the evidence, or if the court is convinced the jury has reached a seriously erroneous result, or if there has been a miscarriage of justice.

Patent Law > Infringement > Burdens of Proof
[HN17] The burden is on the patent holder to prove damages by a reasonable probability.

Civil Procedure > Jury Trials > Jury InstructionsCivil Procedure > Relief From Judgment > Motions for New Trial
[HN18] The standard of review of jury instructions on a motion for a new trial is as follows: Instructions must be viewed in their entirety. A new trial is permissible when it is clear that error in the instructions as a whole was such as to have misled the jury. In addition, the error must prejudice the defendant's case.

Patent Law > Novelty & Anticipation
[HN19] The presumption that the inventor has knowledge of all the art has been rejected by the Court of Appeals for the Federal Circuit.

Civil Procedure > Jury Trials > Jury Instructions
[HN20] Where a party has failed to make any request for an instruction with regard to knowledge of the ordinary person skilled in the art, under Fed. R. Civ. P. 51, that party has waived any objection based on that omitted instruction.

Patent Law > Infringement > Exclusive Rights
[HN21] Where a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing. Such an affirmative duty includes, inter alia, the duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity.

Patent Law > Infringement > Exclusive RightsPatent Law > Infringement > Defenses
[HN22] While counsel's opinion with respect to a patent is evidence of good faith, it is not dispositive, and it is necessary to look at the totality of circumstances presented by a case in determining whether infringement is willful. Willfulness may include a determination that the infringer had no reasonable basis for believing it had a right to do the acts.

Patent Law > Infringement > Exclusive RightsPatent Law > Infringement > Defenses
[HN23] A memorandum containing only bold, conclusory, and unsupported remarks regarding validity is inadequate for reasonable reliance.

Patent Law > Infringement > Exclusive RightsPatent Law > Infringement > Defenses
[HN24] An organization on notice that it is infringing another's patent should inquire into the validity of the patent before rather than after the alleged infringing activities begin.

Patent Law > Remedies > Damages
[HN25] Multiplication of damages depends upon the degree of bad faith exhibited by the defendant.

Patent Law > Remedies > Costs & Attorney Fees
[HN26] An award of reasonable attorney's fees pursuant to *35 U.S.C.S. § 285* is appropriate where there has been a finding of willful infringement.

Patent Law > Remedies > Damages
[HN27] The Supreme Court has recently construed *35 U.S.C.S. § 284* to require that prejudgment interest ordinarily be awarded.

Patent Law > Remedies > Damages
[HN28] The standard governing the award of prejudgment interest under *35 U.S.C.S. § 284* should be consistent with Congress' overriding purpose of affording patent owners complete compensation. In light of that purpose, the Supreme Court concluded that prejudgment interest should ordinarily be awarded. In the typical case an award of prejudgment interest is necessary to ensure that the patent owner is placed in as good a position as he would have been in had the infringer entered into a reasonable royalty agreement. An award of interest from the time that the royalty payments would have been received merely serves to make the patent owner whole, since his damages consist not only of the value of the royalty payments but also of the foregone use of the money between the time of infringement and the date of the judgment.

Patent Law > Remedies > Damages
[HN29] The district court may "fix" the interest and select an award above the statutory rate, or select an award at the prime rate. Once the claimant has affirmatively demonstrated that a higher rate should be used, the district court may fix the interest or that higher rate.

COUNSEL: [**1]

Bruce M. Stargatt, Esquire, Richard H. Morse, Esquire, Young, Conaway, Stargatt & Taylor, Wilmington, Delaware, John O. Tramontine, Esquire, Eric C. Woglom, Esquire, Jesse J. Jenner, Esquire, Richard M. Barnes, Esquire, Douglas J. Gilbert, Esquire, Fish & Neave, New York, New York, for Plaintiff.

Paul E. Crawford, Esquire, Connolly, Bove, Lodge & Hutz, Wilmington, Delaware, John D. Gould, Esquire, Douglas J. Williams, Esquire, Mark J. DiPietro, Esquire, Merchant, Gould, Smith, Edell, Welter & Schmidt, Minneapolis, Minnesota, for Defendant.

JUDGES:

Walter K. Stapleton, Circuit Judge. n1

n1 Honorable Walter K. Stapleton, United States Circuit Judge for the Third Circuit, sitting by designation.

OPINIONBY:

STAPLETON

OPINION:

[*1370] STAPLETON, Circuit Judge:

This is a patent infringement action brought by plaintiff Schering Corporation against defendant Precision-Cosmet Co., Inc. ("P-C"). On March 11, 1985, a jury returned a general verdict for Schering in the amount of $1,263,482, along with answers to a number of interrogatories. Currently before the Court are motions by both parties. P-C has moved for Judgment Notwithstanding the Verdict ("JNOV") and, in the alternative, for a [**2] new trial. Schering has moved for an award of prejudgment interest, increased damages, and reasonable attorney's fees.

I. MOTION FOR JNOV

[HN1] The moving party is entitled to a JNOV when the Court is convinced:

> [*1371] (1) that reasonable persons could not in light of . . . [the] evidence have found the facts necessary to support the jury's verdict; *or* (2) that the facts properly found cannot in law support that verdict. If, on the other hand, the court is convinced that reasonable persons could have found in light of . . . [the] evidence the facts necessary to support in law the jury's verdict, denial of the motion for JNOV is required.

Weinar v. Rollform, Inc., 744 F.2d 797, 805 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co., 722 F.2d 1542 (Fed. Cir. 1983)).*

[HN2] The Federal Circuit has also set forth guidelines that a court must follow in considering a motion for JNOV. Under these guidelines, a court must:

> (1) consider all the evidence; (2) in a light most favorable to the non-mover; (3) drawing reasonable inferences favorable to the non-mover; (4) without determining credibility of witnesses, and (5) without substituting its choice [**3] for that of the jury between conflicting elements in the evidence.

Connell v. Sears, 722 F.2d at 1546. Further, [HN3] where as here the issue raised is validity, "the true question is whether [defendant], which bore the burden, *35 U.S.C. § 282,* submitted such evidence as would preclude a reasonable jury from reaching a verdict of validity." *Weinar v. Rollform, 744 F.2d at 805.* In this regard, it is well to note that the question presented by a motion for JNOV is *not* whether the district court would have found the invention obvious as though there had been no trial before a jury. *Id.* Rather, the question is whether the jury's verdict that the Schering patent is valid (i.e. has not been proved invalid) is supported by substantial evidence. *Id.* (citing *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp., 739 F.2d 604 (Fed. Cir. 1984)).*

Notwithstanding these principles, P-C argues that the trial court may review the issue of validity de novo. In so doing, P-C relies upon the Federal Circuit's recent statement in *E.W.P. Corp. v. Reliance Universal, Inc., 755 F.2d 898, 905 (Fed. Cir. 1985),* that validity "is a question of law and that question is freely [**4] reviewable by this court." *E.W.P. Corp.*, however, was not tried before a jury. In *Connell v. Sears*, the court explained that [HN4] though obviousness is indeed a question of law, it is an issue that may properly be submitted to a jury, in the same manner that other legal questions, such as negligence, are regularly submitted to juries in personal injury cases. *722 F.2d at 1547; Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1514-15 (Fed. Cir. 1984).* Thus, though P-C is clearly correct that obviousness is a question of law, it is equally clear that when faced with a motion for JNOV concerning a verdict of validity, consideration of that motion by the trial court is limited by the standard of

review and guidelines set forth in *Connell v. Sears* and *Weinar v. Rollform*.

A. *The Obviousness Issue*

The parties agree, for purposes of the motion for JNOV and a new trial, that the claimed invention is a gas permeable hard contact lens made principally of tertiary butyl styrene ("TBS"). P-C contends that such an invention would have been obvious to one with ordinary skill in the art in light of seven items of prior art, only one of which was before the Patent Examiner: [**5] (1) the Fatt article (DX-212AG); (2) Larke & Tighe U.K. Patent No. 1,394,056 (DX-212M); (3) Gaiser U.S. Patent No. *2,674,743* (DX-212B); (4) the Salame article (DX-212H); (5) Lundberg U.S. Patent No. *4,057,598* (DX-212C); (6) the Dow brochures (DX-212AH, DX-212AI), and (7) Larke U.K. Patent No. 1,395,501 (DX-212N).

Defendants contend that the above prior art paved a clear path to the inventor's decision to substitute the higher alkyl styrenes, including TBS, in a hard contact lens formulation, in order to provide improved gas permeability.

I conclude, however, that there is substantial evidence in the record supporting the conclusion that the subject matter of the invention of the Schering patent [*1372] taken as a whole would not have been obvious at the time the invention was made to a person of ordinary skill in the art.

A principal contention made by P-C with respect to the question of obviousness is that the high gas permeability of a TBS lens would be predicted in 1977 on the theory that the addition of bulkier side groups to a polymer creates a more "open structure" (lower density) for the passage of oxygen. P-C presented the testimony of Dr. Salame for purposes of explicating [**6] this theory. Both of Schering's experts, however, expressly opined that the higher permeability of TBS would not have been predictable and provided reasons for their opinions. Dr. Hoehn expressly stated that the permeability of TBS was not predictable. (Tr. 1620). He explained that, contrary to Dr. Salame's theory, permeability of a material is not a property of the polymer; it is instead a property of the article made from the polymer. (Tr. 1618). According to Dr. Hoehn, predicting permeability with any degree of success depends on whether one has studied the article made from the polymer. *Id.*

Dr. Fatt testified that he would not be able to predict increased permeability of a polymer merely on the basis that bulkier side groups were added. (Tr. 343). Dr. Fatt opined that gas permeability was predicted upon two components -- the speed at which the molecule traveled through the plastic and the solubility of the gas in the plastic -- and that these components could offset one another with the result that addition of a bulkier group would not necessarily lead to increased permeability. (Tr. 343). He also indicated that the lower density of a polymer did not always lead to increased [**7] permeability. (Tr. 342).

Dr. Fatt further testified that the increased permeability of ethyl, isopropyl and tertiary butyl styrene over stryene and methyl styrene was unexpected. (Tr. 270-71). Mr. Deichert of Bausch & Lomb also acknowledged that the permeability of TBS was "surprising and unexpected". (Tr. 1093).

P-C contends that the Larke & Tighe patent (DX-212M) teaches one skilled in the art that the addition of bulkier side groups, by providing more open space, will improve oxygen permeability. P-C's reference here is not to any teaching concerning the compositions claimed in the Schering patent but, rather, to the following language of the Larke & Tighe patent:

> Although the invention is not limited to any particular theory, it is believed that the bulky side groups attached to the polymer chain disrupt the chain symmetry and regularity of the polymer giving a more open structure having increased gas permeability.

Given the contrary testimony of Dr. Fatt and Dr. Hoehn as to the understanding of those working in the art at the relevant time, the jury was not bound to conclude that the artisan of ordinary skill would take this theoretical speculation at face value. Testimony [**8] to the contrary by Drs. Hoehn and Fatt represented substantial evidence that increased permeability was not predictable.

Dr. Fatt further testified that the use of TBS in a hard contact lens would not have been obvious to him from the Lundberg patent (DX-212C). He explained that the patent disclosed TBS as one of 25 to 30 monomers for the hydrophobic block of a copolymer and that one of the 25 possible uses for the copolymer was a soft, not *hard*, contact lens. He indicated that there was no mention of gas permeability in Lundberg. (Tr. 279-293). He explained that out of the many possible combinations of uses with different monomers, disclosed by Lundberg, it would not have been obvious to pick out the use of TBS in a soft lens, let alone in a hard one. (Tr. 292).

As to the Gaiser patent (DX-212B), Dr. Fatt indicated that neither TBS nor any other alkyl styrene claimed in the Schering patent is mentioned in Gaiser. (Tr. 297). Moreover, both Drs. Fatt and Salame testified that the substituted styrenes referred to by Gaiser constituted a class of more than one hundred compounds.

(Fatt Tr. 297-98; Salame Tr. 1271-72). Most significantly, [*1373] Fatt testified that Gaiser did [**9] not mention anything with respect to the improved gas permeability that resulted from the use of certain substituted styrenes. (Tr. 297).

While Dr. Salame testified that the increased permeability of TBS would have been obvious, [HN5] the jury was entitled to reject his testimony if they did not find it credible. And it is not the province of this Court to weigh the credibility of Salame's testimony against the testimonies of Hoehn and Fatt. *Connell v. Sears, 722 F.2d at 1546-47.*

The question here is whether P-C, in light of its burden to prove invalidity by clear and convincing evidence, submitted such evidence as would preclude a reasonable jury from reaching a verdict of validity. I conclude that it did not and that the jury's conclusion on obviousness was supported by substantial evidence.

B. *Anticipation*

P-C argues that the Gaiser patent, which teaches that contact lenses can be made of styrene or substituted styrenes, anticipates a number of the asserted claims of the Schering patent. P-C points to the testimony of Dr. Fatt and Dr. Loshaek. Dr. Fatt testified that he would have understood the reference to substituted styrenes in the Gaiser patent to mean divinyl benzene. [**10] (Tr. 295-296). He also indicated that a contact lens of divinyl benzene, having a substantial amount of ethyl styrene as an impurity, would come within the language of claim 1 of the patent-in-suit. Dr. Loshaek testified that the term "substituted styrenes" could mean the styrenes he had been testifying about, including TBS. (Tr. 1460-61).

Dr. Fatt also testified, however, that neither TBS, isopropyl styrene, ethyl styrene, nor any other substituted styrene are mentioned in the Gaiser patent. (Fatt 295-297). Dr. Fatt also stated that Gaiser did not mention gas permeability with respect to substituted styrenes. (Tr. 297). In addition, both Drs. Fatt and Salame testified that the class of substituted styrenes includes more than one hundred compounds. (Fatt Tr. 297-298; Salame Tr. 1271-72).

As recently stated by the Federal Circuit:

> [HN6] A party asserting that a patent claim is anticipated under *35 U.S.C. 102* must demonstrate . . . identity of invention. In cases like this, identity of invention is a question of fact, and one who seeks such a finding must show that each element of the claim in issue is found, either expressly described or under principles of inherency, in a single [**11] prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice. . . . (citations omitted).

Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771-72 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026, 104 S. Ct. 1284, 79 L. Ed. 2d 687 (1984).

[HN7] The general rule is that a prior genus does not anticipate a later species. I Chisum, *Patents* § 3.02[2] (1985); *see In re Ruschig, 52 C.C.P.A. 1238, 343 F.2d 965 (C.C.P.A. 1965).* If, however, it is possible to derive a class of compounds of lesser scope than the genus disclosed in a prior art reference on the basis of preferences ascertainable from the remainder of the reference, anticipation may be found. *E.g., Application of Schaumann, 572 F.2d 312, 316 (C.C.P.A. 1978); In re Petering, 49 C.C.P.A. 993, 301 F.2d 676, 681 (C.C.P.A. 1962).* The anticipating reference must contain within its four corners a sufficient description to enable one to practice the invention without experimentation or inventive skill. *Philips Elec. & Pharmaceutical Indus. Corp. v. Thermal & Elec. Indus., Inc., 450 F.2d 1164, 1169 (2d Cir. 1971); Dewey & Almy Chem. Co. v. Mimex* [**12] *Co., 124 F.2d 986, 990 (2d Cir. 1942);* I Chisum, *Patents* § 3.04[1][6] (1985). *See CBS v. Sylvania Electric Prod., Inc., 415 F.2d 719, 725 (1st Cir. 1969)* (test is whether the prior art reference "describes the invention with sufficient clarity and specificity so that one skilled in the art may practice the invention without assistance from the patent claimed to have been anticipated.")

[*1374] Based on these principles, I conclude that there was substantial evidence in the present case from which a reasonable jury could conclude that Gaiser did not anticipate the various claims of the Schering patent. Indeed, given the text of the Gaiser patent and the undisputed evidence with respect to the number of compounds coming within the class of substituted styrenes, it is difficult to understand how the jury could have concluded otherwise. Gaiser does not mention any particular substituted styrene, makes no references to the permeability of specific substituted styrenes, and provides no basis whatever for preferring any sub-group of substitute styrenes over other substituted styrenes for use in making contact lenses. Given the fact that substituted styrenes comprise a [**13] class in excess of one hundred compounds, it seems clear that the elements of the claimed invention, namely TBS, were not adequately described by Gaiser for purposes of identification; and that one of ordinary skill in the art would have had to engage in extensive experimentation to get from Gaiser to the Schering invention.

In re Petering and *In re Schaumann*, cases relied on by P-C, both involved situations where a reference disclosing a broader group of compounds was narrowed to a small, definite and limited class of compounds by preferences expressed in the remainder of the disclosure. In the present case, there was evidence indicating that Gaiser would not have pointed one toward a more limited class of substituted styrenes, such as, for example, the alkyl styrenes disclosed by the patent-in-suit.

C. *New Use For Old Substance Issue*

P-C argues that as a matter of law claims 1, 15, 18, 21, 25 and 27 are invalid as reading on a homopolymer of TBS, which is admittedly an old composition. P-C predicates its argument upon the well-established doctrine that [HN8] a new use for an old substance is not patentable. *In re Thuau, 30 C.C.P.A. 979, 135 F.2d 344 (C.C.P.A. 1943).* [**14] Thus, P-C argues that the terms "contact lens" and "buttons" appearing in the preambles of the various challenged claims merely describe a new use for TBS.

I conclude, however, that rather than merely claiming a new use for TBS, the Schering patent discloses a new composition *made* from TBS, i.e., a hard gas permeable contact lens or button. In *Thuau*, the applicant attempted to claim a compound that he had failed to "change in any way." *Id.* at 347. Here, the Schering patent discloses more than the mere chemical composition TBS; it claims contact lenses that have been cut and shaped from the raw compound itself. Such a modification is legally significant and prevents the challenged claims from falling under the doctrine of *In re Thuau*.

[HN9] "The rule that no product patent may issue for discovery of a new use for an old product or process is tempered by the 'doctrine of slight changes.'" Chisum, I *Patents* § 1.03[8] [b] at 1-171 (1985). The doctrine of slight changes extends to the area of chemical compounds. *Id.* at 1-174. That the modification of an old compound into a new patentable one may indeed be slight is illustrated by *Application of Wiggins, 55* [**15] *C.C.P.A. 1356, 397 F.2d 356 (C.C.P.A. 1968).*

Wiggins sought to patent a compound (referred to by the court as 0[2]) because of its analgesic and pain relieving activity in humans. One of Wiggins' claims rejected by the examiner and Board of Appeals prescribed a dosage of 0[2] from "about 10 milligrams to about 1000 milligrams." *Id.* at 358. The prior art consisted of an article by Wolf describing the exact same compound and its use in protecting mice from x-ray radiation. Wolf did not suggest the use for 0[2] discovered by Wiggins, nor did Wolf suggest administering 0[2] in the 10 to 1000 milligram range disclosed by Wiggins. The Board of Appeals rejected the application on the ground that Wiggins had "discovered a new use for an *old* composition." *Id.* at 359 n. 5 (emphasis supplied by Board). The court disagreed, finding that Wiggins had discovered a new composition since the amounts of 0[2] employed by Wiggins in his composition were different from [*1375] the amounts that Wolf had administered in his experiments. *Id.* at 359-60.

In light of *Wiggins*, wherein [HN10] a mere change in the *amount* of a compound was deemed sufficient to change an old composition [**16] into a new one, it would appear to follow that the transformation of TBS into a contact lens involves the creation of a new composition.

In arguing to the contrary, defendants rely heavily upon *Application of Benner, 36 C.C.P.A. 1081, 174 F.2d 938 (C.C.P.A. 1949).* In that case, the applicant argued that he had changed the shape of the compound at issue. The court rejected this argument because the applicant had failed to describe the purported change in shape in the claims of the patent. *Id.* at 942-43. Moreover, the court refused to recognize the introductory phrases of the challenged claims -- which recited a "ball mill lining element" -- for purposes of showing that the compound described in the claims had been shaped into a particular article, i.e., a new composition. P-C similarly argues that the challenged claims of the Schering patent, as distinct from their preambles, merely describe TBS, and that Schering cannot use the preambles, which describe contact lenses and buttons, to further limit what is already defined by the claims themselves.

After *Benner*, [HN11] the Court of Claims and Patent Appeals in *Kropa v. Robie, 38 C.C.P.A. 858, 187 F.2d 150 (C.C.P.A. 1951),* [**17] set down guidelines for determining when the introductory phrase of a claim would be permitted to limit the claim itself. The court indicated that the preamble would be permitted to limit a claim where it "was deemed essential to point out the invention defined by the claim or count," that is, where "the preamble was considered necessary to give life, meaning and vitality to the claims or counts." *Id.* at 152. The court performed an exhaustive analysis of prior precedent and found *inter alia*:

> The preamble is a limitation where it specifies an article or composition in which there inheres a field of specific use, and the constituents of the article which are recited in the portion of the count following the preamble are old compounds not theretofore known to be useful in such an article.

Id. at 159. [HN12] The Court of Appeals for the Federal Circuit has continued to look to the preamble when "necessary to give meaning to the claim and properly define the invention." *Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 896 (Fed. Cir. 1984), cert. denied, 469 U.S. 857, 53 U.S.L.W. 3239, 83 L. Ed. 2d 120, 105 S. Ct. 187 (1984).*

In the present case, the words [**18] "contact lens" and "button" are essential to point out the invention defined by the claims. It is only by reference to the introductory phrase of the challenged claims that it can be known that the subject matter defined by the claims is comprised as a contact lens or as a button adapted to be formed into a lens. In so holding, I note that [HN13] "claims should be so construed, if possible, as to sustain their validity." *ACS Hosp. Systems, Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir. 1984).*

D. *Structural Similarity*

P-C contends that a hard contact lens of TBS was obvious because TBS is an "isomeric homolog" of the prior art styrene or methyl styrene hard contact lenses.

[HN14] While it is true that close structural similarity between prior art compounds and those that are claimed may be an indicia of obviousness, the subject matter of the invention as a whole may be non-obvious if the claimed compound has unexpected properties. *Application of Payne, 606 F.2d 303, 314 (C.C.P.A. 1979); In re Papesch, 50 C.C.P.A. 1084, 315 F.2d 381 (C.C.P.A. 1963).*

In the present case, the jury was presented with substantial evidence upon which it could reasonably have concluded that [**19] a lens of TBS had such unexpected properties as to rebut any inference that might be drawn from structural similarity. Dr. Fatt, for example, testified that the two alkyl styrenes preferred by the Schering patent, TBS and isopropyl styrene, as well as ethyl styrene, all demonstrated unexpected increases in gas permeability over [*1376] the prior art styrene and methyl styrene. (Fatt Tr. 270-71).

II. MOTION FOR A NEW TRIAL

P-C moves in the alternative for a new trial on the grounds that (1) the verdict with respect to a number of issues is against the weight of the evidence; (2) the damages are excessive; and (3) errors in certain of the jury instructions prejudiced defendant's case.

[HN15] A motion for a new trial differs from a motion for JNOV in that:

> A motion for a directed verdict or for judgment n.o.v. raises the legal sufficiency of the evidence, and is to be sharply distinguished from a motion for a new trial on the ground that the verdict is against the weight of the evidence. The latter motion is addressed to the sound discretion of the trial court, which may set aside the verdict as contrary to the preponderance of the evidence although a directed verdict or judgment [**20] n.o.v. is not justified (footnote omitted).

6A J. Moore, *Moore's Federal Practice* § 59.08(5) (2d ed. 1984) (hereinafter Moore, *supra*). [HN16] The standard of review in considering a motion for a new trial is most often formulated in one of three ways. Thus, a new trial will be granted if the verdict is against the *clear* weight of the evidence, *Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 626 (Fed. Cir. 1985);* 6A Moore, *supra* § 59.08(5) (emphasis added), or if the court is convinced the jury has reached a "seriously erroneous result," *Herman v. Hess Oil Virgin Islands Corp., 379 F. Supp. 1268, 1271 (D.V.I. 1974), aff'd, 524 F.2d 767 (3d Cir. 1975),* 6A Moore, *supra*, § 59.08(5), or if there has been a miscarriage of justice. *Parsons v. Doctors For Emergency Services, 81 F.R.D. 660, 662 (D. Del. 1979);* Moore, *supra* § 59.08(5).

A. *Infringement By Saturn II Lens*

P-C contends that the jury's finding of infringement of the Schering patent by the Saturn II lens is against the weight of the evidence. P-C argues that the Saturn II, because of its soft skirt, is fundamentally different from the hard contact lens claimed by [**21] the Schering patent and could not have infringed the Schering patent either literally or under the doctrine of equivalents. I conclude, however, that the clear weight of the evidence does not warrant overturning the jury's finding of infringement with respect to the Saturn II.

P-C admits that the Saturn II lens is characterized by a hard center. Dr. Fatt testified that the portion of the Saturn lens that its wearer looks through is hard, and that, as far as vision is concerned, the Saturn II is a hard contact lens. (Fatt Tr. 385). P-C admits (Def. Br. 36) that the hard portion of the Saturn II functions to correct astigmatism and there was testimony during trial that one of the advantages of the hard lens over the soft is that the hard lens corrects astigmatism.

Since the asserted claims of the Schering patent are not closed, the addition of the soft skirt to the hard center of Saturn II did not preclude a finding of literal infringement by the jury. In addition, the jury was entitled to conclude that Saturn II infringed under the doctrine of equivalents -- especially in light of Dr. Fatt's testimony.

I am not persuaded that the verdict of infringement was clearly not based upon [**22] a preponderance of

the evidence, or that there has been a miscarriage of justice with respect to this issue.

B. *The Question Of Validity*

P-C submits that for the same reasons it is entitled to a JNOV on the issues of obviousness and anticipation, it is alternatively entitled to a new trial on those issues on the ground that the jury's verdict is against the weight of the evidence. Having already discussed much of the relevant testimony and evidence with respect to this matter, I need not repeat it here.

Suffice it to say that I am unable to conclude that the jury's determination respecting validity was contrary to the clear weight of the evidence.

[*1377] C. *Damages*

P-C contends that Schering failed to satisfy its burden of showing what a reasonable royalty would be, and that the jury's award is excessive and against the weight of the evidence.

Schering introduced evidence as to what would be a reasonable royalty for P-C's infringement through the testimony of Dudley Smith, an expert on patent licensing. Basically, Mr. Smith concluded that after a hypothetical licensing negotiation, the parties would have agreed to a 50/50 split of profits which he translated into [**23] a royalty based upon 30% of the gross projected sales prices for all lenses made by P-C. P-C did not challenge Mr. Smith's credentials or experience at trial and he is clearly a well qualified expert on licensing. Notably, P-C did not offer the expert testimony of any licensing witness of its own.

Mr. Smith provided extensive testimony explaining how he arrived at his recommended reasonable royalty. He explained that the procedure for determining a reasonable royalty is to assume a hypothetical negotiation between a willing licensor and willing licensee who are attempting to agree on a reasonable royalty rate for a license under the patent-in-suit. Smith constructed the hypothetical negotiation by using what he considered a generally recognized royalty rate for patent licenses and then considering the effect of numerous factors that might increase or decrease the initially chosen rate. Smith evaluated the effect of approximately seventeen factors in forming his opinion as to an appropriate royalty. (Tr. 584-618).

Defendant argues essentially that Smith's opinion is unsupportable when viewed against the evidence relating to (1) other licenses in the contact lens field; (2) established [**24] royalty rates in the optical and chemical industries; and (3) other gas permeable lenses on the market.

P-C's first argument is that it produced uncontroverted evidence of royalty rates currently in place in the contact lens industry, i.e., the Erickson agreement (DX-256), n2 which provides a royalty rate of 5% on net sales, and the Bausch & Lomb agreement, which provides a 10% royalty of net sales on the sale of Saturn II lenses by B & L (5% to P-C and 5% to Erickson). (DX-135). P-C further points to a number of statements by Smith that P-C claims undermine his opinion concerning the royalty that ought to apply to the present case. According to P-C, Smith allegedly agreed with a statement from the Finnegan article that most royalty rates are 5 to 6% based on net sales, he admitted that seldom do licensees use profit as a basis for calculating royalties, and also agreed with a statement that in the optics and chemical fields royalties are based upon net sales, not gross profits, and that royalties range from 2% to 5%.

n2 This agreement provided for the transfer to P-C of the Saturn lens technology from Erikson.

[**25]

With respect to the Erickson agreement, upon which P-C particularly relies in pressing its motion for a new trial on the issue of damages, Smith testified that it was not "analogous" to the agreement that would have been hypothetically negotiated between Schering and P-C. Smith indicated that under the *Georgia Pacific* analysis the patent at issue is assumed valid and infringed during negotiations. The consequence of this assumption is that the royalty tends to increase. (Tr. 587, 687). Smith distinguished Erickson on the ground that it did not involve a patent presumed to be "invalid and infringed." (Tr. 687).

Moreover, while the Erickson agreement licensed P-C under Erickson's patent, it did so at a time (1977) when the Saturn lens had a PMMA center and was years away from being ready for submission to the FDA with a TBS center (which P-C did not do until 1984), and thus was far less valuable to P-C than a license in July 1981 under Schering's patent. In addition, the royalty under the Erickson agreement was accompanied by a substantial fixed payment (DTX-256), and there is no evidence that Erickson was ever a gas permeable hard contact lens supplier so that P-C would be a competitor [**26] of Erickson. Smith [*1378] indicated that each of these factors would have a substantial impact on the royalty rate.

P-C's claims that Smith agreed with actual statements from the Finnegan article relating to the rate of typical industry royalties and the rate of royalties in

the field of optics and chemicals are belied by the record. Smith testified that he could *not* agree with the proposition that common industry royalty rates were 5-6% of net sales for two reasons. First, he had not seen the survey on which the statement was based, and second he explained that the statement of typical rates does not show whether a patent license is involved "let alone a patent that had been held valid and infringed." (Tr. 272). Smith was also unable to agree with the statement concerning typical royalty rates in the chemical and optics industries. He explained that the statement was too broad, and that he would need to know what type of license was being referred to, since royalty rates varied according to the nature of the license. (Tr. 677-78).

Moreover, there was testimony by Smith relating to the Finnegan article that actually supported his calculations of a reasonable royalty. He [**27] indicated that the 5% royalty rates based on net sales referred to in the Finnegan article related to "commercial cases where . . . none of the patents have been held valid and infringed." He pointed out on the other hand that Finnegan described a case where "the Court awarded a reasonable royalty which equalled forty-eight percent of the patent infringer's profits." (Tr. 714).

Smith also testified at several points explaining why he calculated his royalty based on projected gross sales of all manufactured lenses rather than net sale of units sold as advocated by P-C. (Tr. 706-709; 1805-1807).

Finally, P-C argues that the rate recommended by Smith was unjustifiably high since the Airlens did not constitute an extraordinarily unique product giving a competitive advantage to the licensee. This factor was, of course, one of many that the jury was free to consider in determining the appropriate royalty. But even if, as P-C contends, the value of the Airlens to a hypothetical licensee was reduced in 1981 because the lens market was occupied by numerous competitors, I am not persuaded that this factor, alone or in combination with any others cited by P-C, constituted evidence that clearly [**28] rebutted Smith's testimony.

Thus, while [HN17] the burden was on Schering to prove damages by a "reasonable probability", *Gyromat Corp. v. Champion Spark Plug Co., 735 F.2d 549, 555 (Fed. Cir. 1984),* I conclude from the foregoing that Schering successfully and persuasively carried this burden. Virtually all of the arguments that P-C now raises with respect to the evidence were addressed and rebutted by Smith. The jury was free to credit his testimony and it is not surprising that it did so given the fact that no expert testimony was offered to contradict his views. n3

n3 *See Hanson v. Alpine Valley Ski Area Inc., 718 F.2d 1075, 1079 (Fed. Cir. 1983)* (discussing the failure of defendant to counter plaintiff's expert license witness with one of its own).

D. *Jury Instructions*

In support of its motion for a new trial, P-C asserts that there were a number of errors of omission and commission in the instructions given to the jury. I remain of the view that the jury was adequately and correctly instructed regarding [**29] the applicable law and further conclude that, in the one area open to reasonable debate, any error that may have crept into the charge would not warrant a new trial.

The parties are in agreement as to [HN18] the standard of review of jury instructions on a motion for a new trial:

> Instructions must be viewed in their entirety. A new trial is permissible when it is clear that error in the instructions as a whole was such as to have misled the jury.

Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1518 (Fed. Cir. 1984). In addition, the error must prejudice the defendant's [*1379] case. *Shatterproof Glass, 758 F.2d at 627.*

1. "*Likely To Carry Burden*"

I declined to give the following instruction requested by P-C:

> If you find that the additional prior art relied on by defendants is more pertinent than the prior art referred to by the Patent Office during the consideration of the application for the Schering patent, then defendants are more likely to carry their burden of proof that the patent is invalid.

This requested instruction takes a comment of the Federal Circuit regarding what juries are likely to do in certain situations and attempts [**30] to convert it into a proposition of law. In my judgment, it would have been more likely to confuse the jury than to help it understand the applicable law.

In addition to being given an explanation of the patent system and what happens in the Patent Office, the jury was correctly instructed that it was required to determine, with respect to each claim, whether the evidence as a whole showed clearly and convincingly

that the subject matter of the invention would have been obvious to one of ordinary skill in the art given the prior art. The vast majority of the evidence tendered at trial was relevant to this issue. One piece of such evidence was that certain of defendant's prior art references were not before the Patent Office when it decided that the statutory requirement of nonobviousness had been met. While P-C chose not to do so, it was free to stress this particular fact to the jury in closing argument. It was not entitled, however, to have the judge single this fact out and tell the members of the jury that it meant that P-C was "more likely" to have carried its burden of proving obviousness. The relevance and importance in any particular case of evidence tending to show that [**31] some prior art references were not before the PTO will depend upon the jury's view of the other evidence bearing on the obviousness issue.

2. *Presumed Knowledge*

P-C complains that the Court failed to charge the jury regarding a presumption that "a hypothetical ordinary person skilled in the art has knowledge of all the art relied on at trial even if the patentees were actually unaware of that art." One problem with this contention is that it does not appear that P-C actually requested an instruction to this effect.

Defendant's "Request For Instruction 19A" requested the following: "You must presume the inventors were aware of all the art, whether or not they were in fact aware of it at that time." In a letter to the Court dated March 7, 1985, P-C requested a slightly different construction: "You must presume that the inventors were aware of all of the relevant art which existed at the time they made the invention, irrespective of whether they personally knew of it." [HN19] The presumption that the *inventor* has knowledge of all the art has been rejected by the Court of Appeals for the Federal Circuit. *Kimberly-Clark v. Johnson & Johnson, 745 F.2d 1437, 1454 (Fed. Cir. 1984)* [**32] ("We hereby declare the presumption that the inventor has knowledge of all material prior art to be dead.") There can, therefore, be no error in this Court's failure to adopt the above two requested instructions.

Second, at the prayer conference [HN20] P-C failed to make any request with regard to knowledge of the ordinary person skilled in the art. Under F.R. Civ. P. 51, P-C has waived any objection based on that omitted instruction.

Finally, even if the instruction had been properly requested and improperly denied, I would be unable to conclude that the error was such as to mislead the jury and prejudice the defendant. P-C is specifically concerned about Salame's Permachor System, since there was testimony from some of Schering's witnesses that persons in the art may not have been aware of that system. (Tr. 176-77, 1613). However, the jury was specifically instructed that Salame's Permachor system was part of the "stipulated or agreed upon prior art." [*1380] (Charge to the Jury, p. 16). The jury was further instructed that, on the issues of obviousness and anticipation, they were to "consider each patent or publication which has been agreed to be prior art." (Charge to the Jury, [**33] p. 25). Finally, the Court defined prior art for the jury as "the knowledge that was previously available to the public" (*id.* at 15) -- not art available to only certain individuals. n4

n4 The Court had previously instructed the jury at the outset of the trial as follows:

> So when we ask ourselves whether the invention described in the patent is new and whether it was obvious, given what had been learned earlier by others, we compare the patent with the prior art, we compare the patent with the pre-existing patents and publications in the same area that reflect what others had learned and discovered before.
>
> The prior art is what was previously available to the public and those practicing this art, and this is what is important. It does not matter whether or not it is shown that the inventor of a patent knew about or received aid from the prior art and what others had discovered.
>
> In order to have a valid patent, somebody has to be able to show that they added something of value to what was previously available to the public.

[**34]

Based on the above, I am confident that the jury was not misled as to the scope and content of the prior art or as to their duty to compare each claim of the patent-in-suit with all of P-C's prior art references.

3. *Old Composition For New Use*

In addition to claiming as a matter of law that six claims of the Schering patent are invalid because they merely disclose a new use for an old compound, *see*

section I.C., *supra*, P-C also contends that it was entitled to an instruction submitting this defense to the jury.

I have already concluded, however, that as a matter of law the Schering claims disclose a new composition. Therefore, P-C was not entitled to an instruction submitting this defense to the jury.

4. *Deichert's Work*

In support of its motion for a new trial, P-C complains of the instruction of the Court regarding claims 18, 27 and 29 of the Schering patent and the issues of whether they were anticipated by Mr. Deichert's work at Bausch & Lomb during August and September of 1977. In support of this contention, P-C relies upon the assertion that "an inventor need only appreciate the *existence* of the subject matter of his invention, but need not fully appreciate [**35] all of the functions or advantages that make it patentable." I do not disagree with this proposition; I do not think it applicable, however, to the issues of whether Deichert's work anticipates claims 18, 27 and 29.

The subject matter of claims 18, 27 and 29 is "an optically clear, non-hydrophilic contact lens" (or a "button adapted to machine" such a lens) having "a gas permeability constant of at least about 10x10-11" and being made of a polymer produced by polymerizing 70% to 100% TBS monomer, 0% to 10% "compatible cross-linking monomer" and 0% to 20% "compatible plasticizer." n5 While I acknowledge, in retrospect, that the matter is not free from doubt, I charged as I did with respect to these claims because, on the record before me, I regarded the presence of a DK value of at least 10 as well as the presence of at least 70% TBS to be part of the definition of the subject matter of these claims and not an inherent characteristic of an invention defined by the other portions of the claims. From this perspective, in order to find the inventions of these claims anticipated by Deichert, the jury would have to conclude not only that Deichert made a lens coming within the scope of the [**36] claims, but also that he appreciated that he had done so. This would include an appreciation that his 70% plus TBS lens had a DK value in excess of 10. This was significant because there was evidence that Deichert had never tested his lens for gas permeability.

> n5 As is clear from the wording of the claims, the percentage of TBS and cross-linking monomer are based on the total weight of the polymer and the percentage of plasticizer is based on the total weight of the polymer and plasticizer.

[*1381] The charge as given was intended to comport with the teachings of *Silvestri v. Grant, 496 F.2d 593 (C.C.P.A. 1974)* and *Knorr v. Pearson, 671 F.2d 1368 (C.C.P.A. 1982)*. If the gas permeability constant of 10x10-11 be regarded as an inherent characteristic of the invention otherwise defined in claims 18, 27 and 29 and these cases are to be distinguished on that basis, it still would not follow, however, that P-C is entitled to a new trial with respect to these claims. I say this because if the jury found, [**37] as it did, that P-C had not carried its burden of proving that Deichert's work anticipated the broader subject matter of the other claims-in-suit, it follows, *a fortiori*, that it did not carry its burden with respect to claim 18, 27 and 29. In this connection, it seems to me that the jury's finding of no anticipation of the other claims strongly suggests, and perhaps requires, a finding that the subject matter of the claims of the Schering patent are limited to hard contact lenses and that Deichert was found by the jury to have worked solely with soft contact lenses.

5. *Infringement*

P-C's final objection to the Court's charge is that it was erroneous to permit the jury to consider the performance characteristics of Schering AIRlens.

The Court's charge stated that Schering had the burden of proving that the accused lenses and buttons infringe the claims of the Schering patent. (Tr. 1901). The Court further instructed the jury at least four times that they should determine infringement by comparing the claims with the accused product. (Tr. 1896, 1901, 1902 and 1904).

With regard to the doctrine of equivalents, the Court instructed the jury:

> In order for the doctrine [**38] of equivalents to apply, however, each element of the claimed invention or its substantial equivalent must be found in the accused product. And the claimed invention and the accused product must perform substantially the same function in substantially the same way to yield substantially the same result.
>
> * * * *
>
> Now, as I have already explained to you, the test of infringement is whether the claims of the patent cover the accused device so that the accused products are to be compared with the claims of the Schering patent and not with the plaintiff's product, the AIRlens.
>
> However, if you reach this issue of whether the accused product and the

> claimed invention perform substantially the same function in substantially the same way to yield substantially the same result, and if you believe that the AIRlens, the plaintiff's product, comes within the scope of the claims of the patent, you may consider the evidence of Schering which compared the performance characteristics of the Airlens with those of the Opus III and Saturn II.

Id., p. 11, Tr. 1904-05.

In this context, it was not error to give the jury permission to consider the performance characteristics of the AIRlens [**39] on the issue of equivalents in the event it concluded that the AIRlens was an embodiment of the invention described in the claims of the Schering patent.

III. SCHERING'S MOTIONS

A. *Increased Damages*

In addition to its general verdict for Schering, the jury answered a number of interrogatories and found, *inter alia*, that P-C had willfully infringed each of the asserted patent claims. Schering now moves for an award of increased damages pursuant to *35 U.S.C. § 284.*

In *Underwater Devices, Inc. v. Morrison-Knudson Co., 717 F.2d 1380, 1389-90 (Fed. Cir. 1983),* the court upheld a treble damage award based on a finding of willful infringement and stated:

> [HN21] Where, as here, a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing. Such an affirmative duty [*1382] includes, *inter alia*, the duty to seek and obtain competent legal advice from counsel *before* the initiation of any possible infringing activity. (Citations omitted).

More recently, the Federal Circuit has recognized that [HN22] while counsel's opinion with respect to a patent is evidence of [**40] good faith, it is not dispositive, and it is necessary to look at the totality of circumstances presented by a case in determining whether infringement is willful. *Central Soya Co., Inc. v. Geo. A. Hormel & Co., 723 F.2d 1573, 1577 (Fed. Cir. 1983).* The Federal Circuit has also indicated that "willfulness may include a determination that the infringer had no reasonable basis for believing it had a right to do the acts." *Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1548 (Fed. Cir. 1984)* (citing *Stickle v. Heublein, Inc., 716 F.2d 1550, 1565 (Fed. Cir. 1983)).*

In the present case, the jury had before it the following evidence of willfulness. P-C knew of Schering's patent prior to P-C's application to the FDA in July 1981 for approval to sell the Opus III contact lenses. (Tr. 898-899). P-C had consulted with counsel concerning the question of infringement of the Schering patent prior to the July 1981 FDA application. (Tr. 432-435). The issue of infringement was discussed at the July 1981 meeting of Frigitronic's Board of Directors and is reflected in the following statement taken from the minutes of that meeting:

> Mr. West presented an article stating [**41] the opinion that gas permeable hard lenses are the product of the future. Our OP346[**] has the highest oxygen permeability of all lenses aside from the silicones. It can be manufactured in our present facility. However, we may be infringing a patent application.

(PTX-84, p. 4). Mr. Ralph E. Crump, President of Frigitronics, Inc., testified that he "assume[d]" that the patent application referred to in these minutes was the Wesley-Jessen (Schering) patent. (Tr. 437-39). n6 There was also evidence that in May-June 1981, P-C made a "blind inquiry" to determine whether Schering would be willing to grant a license under its patent. To conceal its identity while making this inquiry, P-C hired a lawyer from Chicago to contact Schering, so that Schering would not suspect that the call came from P-C or P-C's counsel, both of whom were located in Minneapolis. (PX-51, 52, 53; Schmidt Tr. 1700; West Tr. 1699). Finally, there was evidence that as of May 1984, P-C continued to receive advice from counsel that it was infringing the patent-in-suit. As stated in the May 15, 1984 minutes of the Board of Directors:

> Our attorneys have said we must invalidate the Schering patent in [**42] order to win this case, since otherwise we would be infringing. They say we have a 60-70% chance based on prior art. (PX-88).

n6 The parties agreed that any statement or admission made by Frigitronics would be binding on P-C as if it had been made by P-C itself (see Charge To The Jury, March 11, 1985, p. 2).

Notwithstanding this evidence that P-C knew it might be infringing Schering's patent, P-C tendered no evidence that it had obtained an opinion from competent counsel analyzing and evaluating the validity of the Schering patent.

In light of the foregoing, my views are in accordance with those of the jury respecting the issue of willful infringement. P-C was on notice from mid-1981 that it was probably infringing the Schering patent. Yet, P-C came forward with little in the way of demonstrating that it relied in good faith upon competent opinion of counsel as to the invalidity of the Schering patent. While P-C apparently had been advised by its attorneys that there was a "60-70% chance" of invalidating [**43] Schering's patent, this opinion does not satisfy the criteria for reasonable reliance spelled out in *Underwater Devices, 717 F.2d at 1390* (Memorandum [HN23] containing "only bold, conclusory, and unsupported remarks regarding validity" is inadequate). Additionally, the May 1984 Statement would appear to have come too late for purposes of demonstrating good faith. [HN24] An organization on notice that it is infringing another's patent should inquire into the [*1383] validity of the patent *before* rather than *after* the alleged infringing activities begin. *Underwater Devices, 717 F.2d at 1390* (emphasis supplied by court).

Since I am in agreement with the jury that Schering made out its case of willful infringement, I will award Schering double damages. I have decided to double the damages rather than treble them for three reasons. First, this is not a case where a successful patented product is introduced to the market and is later copied by the alleged infringer. P-C presented testimony that it had been developing its contact lenses for approximately two years before becoming aware of the Schering patent. The same testimony indicated that P-C began working with TBS without knowledge [**44] that TBS had ever been used in a contact lens. (Tr. 823-836). [HN25] "Multiplication of damages depends upon the degree of bad faith exhibited by the defendant," *Trio Process Corp. v. L. Goldstein's Sons, Inc., 638 F.2d 661, 662-63 (3d Cir. 1981),* and the fact that P-C developed its lenses independently significantly diminishes the degree of its culpability.

Second, while P-C did not satisfy its affirmative duty to obtain some reasonable basis for believing in the invalidity of the Schering patent before commencing production of its lenses, it has not litigated this case in bad faith. By the time of trial, counsel for P-C, based upon the prior art and the testimony of a highly qualified expert, Mr. Salame, had developed litigable issues with respect to validity and I am confident that P-C and its counsel believed in the merits of its defense at trial.

Finally, while wholly justified given the record before it, I believe the jury's evaluation of damages was on the high side of the permissible range.

B. *Attorney's Fees*

Schering moves for [HN26] an award of reasonable attorney's fees pursuant to *35 U.S.C. § 285.* Such an award is appropriate where, as here, there has been a finding of willful [**45] infringement. *E.g., Kori Corp. v. Wilco Marsh Buggies & Draglines, Inc., 761 F.2d 649 (Fed. Cir. 1985); Central Soya Co., Inc. v. Geo. A. Hormel & Co., 723 F.2d 1573, 1577-78 (Fed. Cir. 1983); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540 (Fed. Cir. 1984).*

C. *Prejudgment Interest*

Schering has moved pursuant to *35 U.S.C. § 284* for an award of prejudgment interest.

There can be little doubt that Schering is entitled to such an award. [HN27] The Supreme Court has recently construed *35 U.S.C. § 284* to require that prejudgment interest ordinarily be awarded:

> [HN28] The standard governing the award of prejudgment interest under § 284 should be consistent with Congress' overriding purpose of affording patent owners complete compensation. In light of that purpose, we conclude that prejudgment interest should ordinarily be awarded. In the typical case an award of prejudgment interest is necessary to ensure that the patent owner is placed in as good a position as he would have been in had the infringer entered into a reasonable royalty agreement. An award of interest from the time that the royalty payments would have been received merely serves to make the patent owner [**46] whole, since his damages consist not only of the value of the royalty payments but also of the foregone use of the money between the time of infringement and the date of the judgment. (footnote omitted)

General Motors Corp. v. Devex Corp., 461 U.S. 648, 655-56, 76 L. Ed. 2d 211, 103 S. Ct. 2058 (1983). P-C has not alleged any facts demonstrating that a prejudgment award would be inappropriate in this case.

Schering relies upon *Lam, Inc. v. Johns-Manville Corp., 718 F.2d 1056, 1066 (Fed. Cir. 1983)* for the proposition that this Court may adopt for prejudgment interest a rate above the Treasury bill rate set by *28 U.S.C. § 1961* for post-judgment, namely the prime

interest rate or the corporate [*1384] bond rate. However, the court in that case stated:

> [HN29] The district court may "fix" the interest and select an award above the statutory rate, or select an award at the prime rate. Once the claimant has *affirmatively demonstrated* that a higher rate should be used, the district court may fix the interest or that higher rate. (citations omitted).

718 F.2d at 1066 (emphasis added). In the present case, Schering offered no evidence which would support [**47] an award above the statutory rate. In *Lam, Inc. v. Johns-Manville Corp.*, the claimant "affirmatively demonstrated and the district court found that Lam borrowed money at or above the prime rate in order to continue its operations." *Id.* A comparable showing has not been made by Schering here. Accordingly, an award of prejudgment interest will be made at the Treasury bill rate as set forth in *28 U.S.C. § 1961,* compounded annually. I also endorse the method by which Schering has calculated the prejudgment interest which it seeks.

IV. CONCLUSION

P-C's motion for a JNOV or a new trial will be denied. Schering will promptly submit an amended form of final judgment which will double the damages found by the jury and will include interest from the time each reasonable royalty payment would have been made until the date of judgment. This final judgment will also award counsel fees in an amount to be hereafter agreed upon or fixed by the Court.

LEXSEE

SYMBOL TECHNOLOGIES, INC., Plaintiff-Appellee, v. OPTICON, INC., and OPTO ELECTRONICS, Defendants-Appellants

No. 90-1409

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

935 F.2d 1569; 1991 U.S. App. LEXIS 12233; 19 U.S.P.Q.2D (BNA) 1241; 33 Fed. R. Evid. Serv. (Callaghan) 1381

June 14, 1991, Decided

PRIOR HISTORY: [**1] Appealed from: U.S. District Court for the Southern District of New York; Judge Wood.

CASE SUMMARY:

PROCEDURAL POSTURE: Defendants sought review of the judgment of the U.S. District Court for the Southern District of New York, which concluded that plaintiff's patents were not proved invalid or unenforceable and found infringement.

OVERVIEW: Plaintiff sued defendants for infringement of certain patent claims. Defendants denied infringement and filed a counterclaim for declaratory judgment that patents were invalid and unenforceable. Following a non-jury trial, the district court concluded that the patents were not proved invalid or unenforceable, and found infringement. On appeal, the court held that expert opinion was admissible without the need to reveal the facts or data underlying his opinion. Because defendant failed to cross examine the witness on those issues, it could not claim error on appeal. Further, references to prior art for determining obviousness were immaterial because the considered references did not disclose or suggest the features critical to the invention's patentability. Thus, the omitted references added nothing to the inquiry and omissions were harmless. The court held that defendant failed to prove by clear and convincing evidence that there was double patenting. Accordingly, the court affirmed.

OUTCOME: The judgment was affirmed because the expert opinion was admissible without the need to reveal underlying facts. The omission of references to prior art for determining obviousness were harmless because the references did not disclose or suggest the features critical to the invention's patentability and were immaterial.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Infringement > Burdens of Proof
[HN1] The party asserting infringement bears the burden of proof by a preponderance of the evidence.

Patent Law > Infringement > Acts of Infringement
[HN2] Determination of patent infringement is a two-step process: the meaning of the claims must be learned from a study of all relevant patent documents; and the claims must be applied to the accused structures.

Evidence > Witnesses > Expert Testimony
[HN3] See Fed. R. Evid. 705.

Patent Law > Specification & Claims > Claim Language
[HN4] By its express terms, *35 U.S.C.S. § 112,* para. 6 permits an element in a claim to be expressed as a means or step for performing a specified function. However, the scope of such a claim is not limitless, but is confined to structures expressly disclosed in the specification and corresponding equivalents. Thus, the statutory provision prevents an overly broad claim construction by requiring reference to the specification, and at the same time precludes an overly narrow construction that would restrict coverage solely to those means expressly disclosed in the specification.

Evidence > Witnesses > Expert TestimonyPatent Law > Infringement > Claim InterpretationPatent Law > Infringement > Burdens of Proof
[HN5] Testimony on the ultimate issue of infringement is permissible in patent cases. Although claim interpretation is a question of law, expert testimony is admissible to give an opinion on the ultimate question of infringement. Fed. R. Evid. 704. The scope of literally infringing "equivalents" under *35 U.S.C.S. § 112,* para. 6 is a factual determination. The full burden of exploration of the facts and assumptions underlying the testimony of an expert witness is squarely on the shoulders of opposing counsel's cross-examination.

Evidence > Witnesses > Expert TestimonyPatent Law > Infringement > Claim Interpretation
[HN6] Fed R. Evid. 705 is fully applicable to patent trials and opinion testimony on infringement of claims under *35 U.S.C.S. § 112* para. 6. The Federal Rules of Evidence are expressly applicable to all proceedings in the courts of the United States, which must include civil suits arising under Title 35. Fed. R. Evid. 101.

Patent Law > Nonobviousness > Tests & Proof of ObviousnessPatent Law > Infringement > Defenses
[HN7] In determining invalidity for obviousness, a court must answer whether the prior art made obvious the invention as a whole for which patentability is claimed. The court does not pick and choose among the individual elements of assorted prior art references to recreate the claimed invention, but rather looks for some teaching or suggestion in the references to support their use in the particular claimed combination.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN8] *35 U.S.C.S. § 103* requires consideration, inter alia, of differences between prior art and claimed invention as a whole.

Patent Law > Novelty & AnticipationPatent Law > Nonobviousness > Tests & Proof of Obviousness
[HN9] While a reference must enable someone to practice the invention in order to anticipate under *35 U.S.C.S. § 102*(b), a non-enabling reference may qualify as prior art for the purpose of determining obviousness under *35 U.S.C.S. § 103.*

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN10] The obviousness inquiry correctly includes review of the evidence offered on the objective indicia of nonobviousness, which included the failure of others to develop the claimed invention and its commercial success. Nonobviousness is suggested by the failure of others to find a solution to the problem which the patents in question purport to solve. Such evidence shows indirectly the presence of a significant defect in the prior art, while serving as a simulated laboratory test of the obviousness of the solution to a skilled artisan.

Patent Law > Nonobviousness > Double Patenting & Terminal Disclaimers
[HN11] With regard to double patenting, *35 U.S.C.S. § 121* will not apply to remove the parent as a reference where the principle of consonance is violated. Consonance requires that the line of demarcation between the independent and distinct inventions that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement. Where that line is crossed the prohibition of the third sentence of § 121 does not apply.

Patent Law > Nonobviousness > Double Patenting & Terminal Disclaimers
[HN12] See *35 U.S.C.S. § 121.*

Patent Law > Nonobviousness > Tests & Proof of ObviousnessPatent Law > Nonobviousness > Double Patenting & Terminal Disclaimers
[HN13] New or amended claims in a divisional application are entitled to the benefit of *35 U.S.C.S. § 121* if the claims do not cross the line of demarcation drawn around the invention elected in the restriction requirement. If that line is crossed, the issue is whether the invention claimed in the later patent would have been obvious in light of the invention claimed in the earlier patent.

Patent Law > Patentable Subject Matter > ProductsPatent Law > Patentable Subject Matter > Processes
[HN14] In the electronic arts, the Patent and Trademark Office has not restricted between claims to an apparatus and to a method of using the apparatus.

Patent Law > Nonobviousness > Double Patenting & Terminal Disclaimers
[HN15] The crux of obviousness-type double patenting inquiry lies in comparison of claims. The judicially created doctrine of obviousness-type double patenting applies when two applications or patents, not drawn to precisely the same invention, are drawn to inventions so very much alike as to render one obvious in view of the other and to effectively extend the life of the patent that would have the earlier of the two issue dates.

Patent Law > Nonobviousness > Double Patenting & Terminal DisclaimersPatent Law > Infringement > Burdens of Proof

[HN16] Double patenting is an affirmative defense, requiring defendant to prove double patenting by clear and convincing evidence.

Patent Law > Jurisdiction & Review > Standards of Review

[HN17] To obtain reversal, appellant must clearly explain why decision below is wrong. It is not the function of an appellate court to search the record in order to reach a conclusion favoring appellant.

Patent Law > Infringement > Claim InterpretationPatent Law > Jurisdiction & Review > Standards of Review

[HN18] The presence or absence of consonance will necessarily depend upon analysis of the involved claims, which are construed as a matter of law. In connection with construing claims, an appellate court is free to examine the prosecution history on appeal even where the trial court erroneously fails to consider it. This is particularly so where there are no underlying findings of fact required for such construction.

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect

[HN19] A finding of gross negligence does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.

COUNSEL:

Arnold Sprung, Sprung Horn Kramer & Woods, of Tarrytown, New York, argued for Plaintiff-Appellee. With him on the brief were Nathaniel D. Kramer and Ira J. Schaefer.

Jeffrey A. Schwab, Abelman Frayne Rezac & Schwab, of New York, New York, argued for Defendants-Appellants. With him on the brief was Michael Aschen.

JUDGES:

Nies, Chief Judge, Newman, and Clevenger, Circuit Judges.

OPINIONBY:

CLEVENGER

OPINION:

[*1571] CLEVENGER, Circuit Judge

Symbol Technologies, Inc., (Symbol) sued Opticon, Inc., and its Japanese parent Opto Electronics, (collectively hereinafter Opticon), in the United States District Court for the Southern District of New York for infringement of certain claims of United [*1572] States Patent Nos. *4,387,297* (*'297* patent), *4,593,186* (*'186* patent), and *4,409,470* (*'470* patent).

Symbol alleged that Opticon's MSH-840, MSH-850 and MSH-860 devices were infringing. Opticon denied infringement and filed a counterclaim for a declaratory judgment that the *'297* and *'186* patents are invalid and unenforceable. Following a non-jury trial, the District Court concluded that the *'297* and *'186* patents were not proved invalid or unenforceable, [**2] and found infringement. n1 *Symbol Technologies, Inc. v. Opticon, Inc., 17 U.S.P.Q.2d 1737, 1990 U.S. Dist. LEXIS 5186 (S.D.N.Y. 1990).* The court entered a liability judgment for Symbol.

> n1 The District Court found that (1) the MSH-840 device infringes (i) claims 1-3, 8, 11, 15, 20, 23 and 36-38 of the *'297* patent, (ii) claims 1-8 and 11-15 of the *'186* patent when used with the decoder with which it was designed to operate and (iii) claims 1-5, 27, 31, 33, 50-54 and 56-62 of the *'470* patent; (2) the MSH-850 device infringes (i) claims 1-3, 8, 9, 11, 15, 17, 20, 23, and 36-38 of the *'297* patent, (ii) claims 1-9 and 11-15 of the *'186* patent when used with the decoder with which it was designed to operate; (3) the MSH-860 device infringes (i) claims 1-3, 5, 6, 8, 11, 15, 20, 21, 23, 36, and 37 of the *'297* patent and (ii) claims 1-9 and 11-15 of the *'186* patent when used with the decoder with which it was designed to operate.

Opticon appeals the judgment of the District Court. This Court has jurisdiction under *28 U.S.C. § 1292*(c)(2) [**3] (1988) to entertain Opticon's appeal. Because no reversible error was committed, we affirm.

I. BACKGROUND

The patents relate to devices that employ lasers to read bar code symbols, and methods of their use. The application that issued as the *'297* patent was filed on February 29, 1980. In the first official action, the examiner required restriction to one of seven species identified as Groups I - VII. The applicants elected Group I claims directed to a light-weight laser scanning head, which matured into the *'297* patent.

The *'297* patent specification refers to two types of previously known laser scanning devices. The first type, often mounted in supermarket and other checkout counters, requires a user to bring the symbol-bearing object to the stationary scanner. Its usefulness is limited to decoding symbols on objects that can be brought to the device. The second type uses a wand or pen that emits a scanning laser beam. The user places the pen in physical contact with the object, then manually drags the pen across the symbol. This second type requires user training because successful decoding depends on pen angle, pressure, and speed of passage as the pen is dragged across the bar [**4] code. Multiple passes of the pen are often required to achieve a single reading. Moreover, the tips of pen scanners tend to scar the bar codes and are not useful on wax coated containers, such as milk cartons, on soft products, such as bagged potato chips, or on reflective aluminum cans.

In contrast, the invention claimed in the *'297* patent is a portable, light-weight laser scanning head that operates without physical contact with the bar code. *See* Figure 1. In gun-like fashion, the user sights the bar code, unobstructed by the device, then depresses a trigger to initiate decoding. Each time the trigger is depressed, the hand-held device sweeps a scanning laser beam laterally across the bar code by use of mirrors. The examiner considered this "aim and shoot" feature to be a novel distinguishing characteristic of the claimed invention over the prior art. All of the asserted *'297* patent claims depend on claim 1, reprinted in the Appendix, which in pertinent part claims the "aim and shoot" feature as:

> (c) miniature optic means . . . to permit the user to conveniently register the laser light beam on the symbol by sighting the symbol along a direct line of sight which does not pass [**5] through the housing;
> (d) miniature scanning means mounted in the light path and in the interior space of the housing for cyclically sweeping the laser light beam across the bar code symbol for reflection therefrom;
>
> * * *
>
> (h) handle means for normally supporting the light-weight laser scanning head in a non-contacting relationship with the symbol during reading thereof; and
> [*1573] (i) manually actuatable trigger means on the housing for initiating reading of the symbol each time the trigger means is manually actuated by the user.

[SEE FIGURE 1 IN ORIGINAL]

Before the *'297* patent issued, the applicants filed a divisional application directed to the originally non-elected Group VI claims, described in the restriction as a "method" of scanning, sensing and decoding bar code symbols. Thereafter, the applicants filed a continuation of the divisional application, which eventually issued as the *'186* patent. The *'186* patent contains apparatus claims 1-10 and method claims 11-15, with the method claims closely corresponding to the original Group VI claims. The broadest asserted apparatus and method claims, reprinted in the Appendix, both require a "trigger" and "repetitively" scan [**6] "the directed laser beam across each symbol for reflection therefrom." Thus, the *'186* patent claims a system that repetitively scans and senses a bar code symbol each time a user depresses the trigger. Each symbol is decoded from repetitive rather than single scans, thereby increasing the likelihood of achieving accurate decoding even for poorly printed symbols. In addition, claim 1 and claim 11 include limiting language for "determining a successful decoding of each symbol," and for "non-manually terminating the reading of each symbol upon the determination of the successful decoding thereof." *See* Appendix. Thus, the invented system alerts the user and automatically stops scanning when the symbol is decoded, permitting rapid and sequential decoding of multiple objects.

The same applicants claimed an advance over the invention of the *'297* patent in an application filed on January 25, 1982, which later issued as the *'470* patent. The *'470* patent specification explains that, because the scanning laser beam of the invention [*1574] claimed in the *'297* patent passes through the inside of the device, "a great deal of interior 'dead' space within the head" is required in order to accommodate [**7] the scanning beam.

In contrast, the *'470* patent discloses a scanning head with a raised rear window that emits the laser beam over the outside top of the device rather than inside its housing. Claim 1 of the *'470* patent, reprinted in the Appendix, includes:

> (g) window means mounted on the housing, and having a light-transmissive window at the rear region in close adjacent confronting relationship with the scanning means thereat, said window being configured and positioned in the light path of said at least one swept beam to permit the latter to pass through the window and unobstructedly travel exteriorly of and past the front and intermediate body regions of the housing.

> whereby the field of view of the swept beam is substantially independent of the predetermined width of the housing due to its exterior transmission outside of the front and intermediate body regions of the housing.

Thus, since the device no longer must accommodate the sweep width of the scanning beam, the invention allows a narrowing of the body of the device, with a corresponding reduction in overall size and weight.

II. INFRINGEMENT

Opticon's first contention on appeal is that Symbol presented insufficient [**8] evidence during its case-in-chief to establish a prima facie showing of infringement. Symbol, as [HN1] the party asserting infringement, bore the burden of proof by a preponderance of the evidence. *Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1361, 219 U.S.P.Q. (BNA) 473, 480 (Fed. Cir. 1983).*

To prove infringement, Symbol offered the expert testimony of Mr. Edward Barkan (Barkan), named as a co-inventor in each of the three patent applications. The court admitted into evidence charts and drawings used by Barkan to demonstrate infringement of the asserted claims, each of which contains "means plus function" limitations as permitted under *35 U.S.C. § 112* para. 6 (1988). The charts show each asserted claim broken down by limitation, with one or more numbers placed next to each limitation. Corresponding numbers identify various structural parts of the accused devices depicted in the drawings. Using the exhibits as a guide, Barkan stated that in his opinion each numbered claim limitation reproduced on the charts was met by the corresponding numbered structure of the device shown on the drawings. Furthermore, Barkan testified that his "understanding of the patent [**9] claims [was] based upon the claims, as well as the specifications, as well as statements made during the prosecution history."

[HN2] Determination of patent infringement is a two-step process: "the meaning of the claims must be learned from a study of all relevant patent documents; and the claims must be applied to the accused structures." *Caterpillar Tractor Co. v. Berco, S.P.A., 714 F.2d 1110, 1114, 219 U.S.P.Q. (BNA) 185, 187 (Fed. Cir. 1983).* Opticon contends that, under *Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 934, 4 U.S.P.Q.2d (BNA) 1737, 1739 (Fed. Cir. 1987), cert. denied, 485 U.S. 961, 99 L. Ed. 2d 426, 108 S. Ct. 1226 (1988),* a party asserting infringement of claims with "means plus function" limitations must demonstrate to the fact-finder how each structure in the accused device, asserted to meet a functional claim limitation, is the same as or equivalent to a corresponding structure disclosed in the specification. Opticon cites the following passage from *Pennwalt* for support:

> Where the issue is raised, it is part of the ultimate burden of proof of the patent owner to establish, with respect to a claim limitation in means-plus-function [**10] form, that the structure in the accused device which performs that function is the same as or an equivalent of the structure disclosed in the specification.

Id.

In the circumstances of this case, however, Fed. R. Evid. 705 provides the answer to whether Symbol made a prima facie [*1575] showing of infringement. n2 At trial, Symbol suggested that the court receive the exhibits representing Barkan's expert testimony without foundation, thus relieving the court and Barkan of the need to "go through lengthy testimony explaining with each infringing device how he found that each element was infringed." Counsel for Opticon responded "I really have no objection except . . . that we have wanted to voir dire." After voir dire, Opticon failed to cross-examine Barkan on the issue that it now asserts fatally flaws the sufficiency of his testimony.

n2 Rule 705, "Disclosure of Facts or Data Underlying Expert Opinion," provides: [HN3]

> The expert may testify in terms of opinion or inference and give reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.

----------End Footnotes---------- [HN4] - [**11]

By its express terms, § 112 para. 6 permits an element in a claim to be expressed as a means or step for performing a specified function. However, the scope of such a claim is not limitless, but is confined to structures expressly disclosed in the specification and corresponding equivalents. Thus, the statutory provision prevents an overly broad claim construction by requiring reference to the specification, and at the same time

precludes an overly narrow construction that would restrict coverage solely to those means *expressly* disclosed in the specification. *Johnston v. IVAC Corp., 885 F.2d 1574, 1580, 12 U.S.P.Q.2d (BNA) 1382, 1386-87 (Fed. Cir. 1989)* (statutory provision acts as restriction on claim scope); *Data Line Corp. v. Micro Technologies, Inc., 813 F.2d 1196, 1201, 1 U.S.P.Q.2d (BNA) 2052, 2055 (Fed. Cir. 1987)* (statutory provision precludes a construction limited to structures expressly disclosed in specification); *D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574, 225 U.S.P.Q. (BNA) 236, 238 (Fed. Cir. 1985)* (statutory provision requires that "limitation *shall* be construed to cover structure described [**12] in the specification *and* equivalents thereof" (emphasis in original)). In short, applying a claim drafted under § 112 para. 6 to an accused structure is not a simple task.

Opticon argues that Barkan must have misunderstood this task, because he testified on the ultimate issue of infringement without discussing in detail equivalency between the structures of the accused devices and the structures disclosed in the patent specifications. However, [HN5] testimony on the ultimate issue of infringement is permissible in patent cases. *Snellman v. Ricoh Co., 862 F.2d 283, 287, 8 U.S.P.Q.2d (BNA) 1996, 2000 (Fed. Cir. 1988), cert. denied, 491 U.S. 910, 109 S. Ct. 3199, 105 L. Ed. 2d 707 (1989)* ("although claim interpretation is a question of law, expert testimony is admissible . . . to give an opinion on the ultimate question of infringement" (citations omitted)); Fed. R. Evid. 704. The scope of literally infringing "equivalents" under § 112 para. 6 is a factual determination. *King Instrument Corp. v. Otari Corp., 767 F.2d 853, 862, 226 U.S.P.Q. (BNA) 402, 408 (Fed. Cir. 1985), cert. denied, 475 U.S. 1016, 89 L. Ed. 2d 312, 106 S. Ct. 1197 (1986).* The responsibility for challenging [**13] the factual underpinnings of the testimony fell squarely on Opticon during cross-examination. *See Smith v. Ford Motor Co., 626 F.2d 784, 793 (10th Cir. 1980), cert. denied, 450 U.S. 918, 67 L. Ed. 2d 344, 101 S. Ct. 1363 (1981)* ("'the full burden of exploration of the facts and assumptions underlying the testimony of an expert witness [is] squarely on the shoulders of opposing counsel's cross-examination'" (citation omitted)); *see also Bryan v. FMC Corp., John Bean Div., 566 F.2d 541, 545 (5th Cir. 1978)* ("rule 705 shifts to the cross-examiner the burden of eliciting the bases of an expert witness' opinion"); *United States v. Santarpio, 560 F.2d 448, 454-55 (1st Cir. 1977), cert. denied sub nom., Schepici v. United States, 434 U.S. 984, 54 L. Ed. 2d 478, 98 S. Ct. 609 (1977)* (under Rule 705, court was entitled to credit expert's conclusion even though expert did not describe and explain the relevance of factors upon which his opinion rested; defendant neither cross-examined on basis for opinion nor attempted to show its inadequacy); *C. Van Der Lely, N.V. v. F. Ili Maschio S.n.c., 221 U.S.P.Q. (BNA) 34, 41 (S.D. Ohio 1983), aff'd, 748 F.2d 1568* [*1576] *(Fed. Cir. 1984)* [**14] (under Rule 705, "cross-examination [is] the proper procedure for the defendant to challenge the accuracy of [the expert's] opinion"). Opticon failed to seize the opportunity, provided by the Rule, to demonstrate that Barkan's opinion testimony was factually incorrect.

Rule 705 functions to abbreviate trials by permitting opinion testimony without factual foundation. We see no reason why [HN6] Rule 705 is not fully applicable to patent trials and opinion testimony on infringement of claims under § 112 para. 6. We have not directly addressed this issue, but have previously applied Rule 705 in a patent case on the issue of damages, stating that an expert need not "reveal the facts or data underlying his opinion . . . because [the defendant] did not cross-examine on this issue and the master did not require otherwise." *Studiengesellschaft Kohle v. Dart Indus., 862 F.2d 1564, 1567, 9 U.S.P.Q.2d (BNA) 1273, 1277 (Fed. Cir. 1988).* Moreover, the Federal Rules of Evidence are expressly applicable to all proceedings in the courts of the United States, which must include civil suits arising under Title 35. Fed. R. Evid. 101. Finally, the specific purpose behind Rule 705 is to [**15] avoid "complex and time consuming" testimony by permitting an expert to "'state his opinion and reasons without first specifying the data upon which it is based.'" Fed. R. Evid. 705 advisory committee's note *quoting* Rule 4515, N.Y. CPLR (McKinney 1963). Patent cases, so often typified by lengthy testimony on complex technical issues, are particularly served by this purpose.

In short, Symbol was permitted to rest its prima facie case on Barkan's expert testimony, including charts, that the patents were infringed, and the District Court was free to accept or reject that evidence. Of course, by resting its case on summary testimony, Symbol was left exposed to a profound risk that Opticon, during its defense or cross-examination of Barkan, would demonstrate that the accused devices were non-infringing under a different and proper construction of the claims. Opticon willingly permitted Symbol to bear this risk, but chose not to expose Barkan's testimony to the glaring light of cross-examination on this issue. Having lost below, Opticon cannot here recoup for its failed litigation strategy. n3 In view of the legal effect of the expedited procedure, we must reject Opticon's contention [**16] that Symbol failed to present a prima facie case of infringement. Since Opticon offers no argument that its products do not infringe on the facts, we need not review infringement itself.

n3 *See* 3 J. Weinstein & M. Berger, Weinstein's Evidence para. 705[01], p. 705-11 (1987):

> Obviously, if further testimony would only solidify the expert's conclusion, his adversary will refrain from further questioning. But if he concludes that the expert has omitted pertinent facts in arriving at his opinion, or has misconstrued them, or is accepting disputed facts as true, or is basing his opinion on someone else's opinion which is in conflict with the established facts, the attorney will wish to probe into the expert's premises.

III. VALIDITY

A. *Obviousness*

Opticon challenges the District Court's conclusion that the inventions of the *'297* and *'186* patents were not proved invalid for obviousness under *35 U.S.C. § 103* (1988). n4 [HN7] We must answer whether "the prior art made obvious the invention as a whole for which patentability [**17] is claimed." *Hartness Int'l Inc. v. Simplimatic Eng'g Co., 819 F.2d 1100, 1108, 2 U.S.P.Q.2d (BNA) 1826, 1832 (Fed. Cir. 1987).* We do not "pick and choose among the individual elements of assorted prior art references to recreate the claimed invention," but rather, we look for "some teaching or suggestion in the references to support their use in the particular claimed combination." *Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 887, 8 U.S.P.Q.2d (BNA) 1468, 1475 (Fed. Cir. 1988).*

n4 The District Court focused on the obviousness of the invention claimed in the *'297* patent. Opticon offers no separate argument on the obviousness under § 103 of the invention claimed in the *'186* patent. We therefore limit our review to the obviousness *vel non* of the invention of the *'297* patent.

[*1577] The District Court found that the prior art consisted of U.S. Patent No. *4,251,798* (the *'798* patent), which describes the Laserchek, and references which describe the Laserscan, [**18] the Verifier 315, the Monitor 101, and the Carton Counter. We review here the teachings of that art.

The *'798* patent is prior art under *35 U.S.C. § 102*(e) (1988). The *'798* patent claims a portable laser scanning head that detects and decodes laser beams reflected from bar codes. The reference discloses a device that can read in a non-contact position:

> This 'depth of field' feature permits a user to scan bar code symbols imprinted both on a flat surface and on a curved surface merely by moving the head towards a position anywhere within 2" of the symbol.

'798 patent, col. 5, line 66 - col. 6, line 6.

During prosecution of the *'297* patent, the *'798* patent was the basis for discussions about the permissible scope of the *'297* patent claims. Indeed, the examiner originally rejected the claimed invention as obvious in light of the disclosure in the *'798* patent. Following an interview with the examiner, the applicants amended the claims to include the handle, trigger and sighting means that appear in claim 1 and are quoted above. The examiner allowed the claims in view of the amendment. The District Court agreed with the examiner's conclusion that the addition of the handle, trigger [**19] and sighting means (described by the District Court as the "aim and shoot" feature) to the self-scanning means distinguished the invention claimed in the *'297* patent from the disclosure in the *'798* patent.

The Laserchek device, a Symbol product, is described in the *'798* patent. Following a demonstration of the device at trial, the District Court found that the Laserchek was a bar code verification device, had no trigger, normally blocked the user's view of the bar code during use, and could not be used in the "aim and shoot" fashion.

The Laserscan was merely a modified version of the Laserchek. The Laserscan consisted of the Laserchek scanning head attached to a console in turn attached to a computer. The District Court found that the Laserscan was not capable of functioning in "aim and shoot" mode because the device had no trigger and obscured the bar code during use.

The Verifier 315 was a bar code reader designed to be used with its feet resting on a surface and its front reading "snout" positioned above the bar code by a small, fixed distance. The District Court found that the device blocked the user's view of the bar code during use and had no trigger.

The Monitor 101 was developed [**20] in the mid-1970's to verify the accuracy of bar codes as they are printed. During printing, the bar codes pass underneath the device, which is fixed above the printing press. The District Court found that the Monitor 101 was neither hand held nor capable of operating in "aim and shoot" fashion.

The Carton Counter counted cartons and was not a bar code reader. However, the device had a trigger, not to initiate decoding of a bar code, but to reset the counter to zero. A brochure describing the Carton Counter was before the examiner and found not to be pertinent. The District Court, finding that the carton counter "is not self-scanning; rather, it must be dragged over the carton edges," concluded that the device "lacks any disclosure, recognition, or teaching of an aim and shoot device." *17 U.S.P.Q.2d at 1746.*

The District Court thus concluded that the invention would not have been obvious in light of the prior art because the considered references did not disclose or suggest the "aim and shoot" feature claimed in parts (c), (d), (h) and (i) of claim 1 of the *'297* patent. We agree. Here the very difference between the claims and the considered art is the "aim and shoot" feature [**21] found critical to the patentability of the invention. *Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 U.S.P.Q. (BNA) 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966)* [HN8] (§ 103 requires consideration, *inter alia*, of differences between prior art and claimed invention as a whole). Thus, a person of ordinary skill in the art, having all of the [*1578] teachings of the considered references before him, would have found no "teaching or suggestion in the references" of the invention claimed in the *'297* patent. *Smithkline Diagnostics, 859 F.2d at 887, 8 U.S.P.Q.2d at 1475.*

However, in reaching its conclusion, the District Court excluded sketches and tentative specifications relating to a device known as the X-Scanner, on the theory that "'prior art' in an obviousness determination [] must . . . be enabling, that is, disclose the disseminated subject matter to the public, in a manner such that one skilled in the art could make and operate such a device." *17 U.S.P.Q.2d at 1740.* [HN9] While a reference must enable someone to practice the invention in order to anticipate under § 102(b), a non-enabling reference may qualify as prior art for the purpose of determining obviousness [**22] under § 103. *Reading & Bates Constr. Co. v. Baker Energy Resources Corp., 748 F.2d 645, 652, 223 U.S.P.Q. (BNA) 1168, 1173 (Fed. Cir. 1984)* (reference that lacks enabling disclosure is not anticipating, but "itself may qualify as a prior art *reference* under § 103, but only for what is disclosed in it" (emphasis in original)); *see Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551, 13 U.S.P.Q.2d (BNA) 1301, 1304 (Fed. Cir. 1989)* ("even if a reference discloses an inoperative device, it is prior art for all that it teaches"). Undisputed evidence demonstrated that the sketches and tentative specifications, together known as the X-Scanner reference, were publicly available more than one year before the effective filing date. The District Court's finding to the contrary is clearly erroneous. While the District Court clearly erred in excluding the X-Scanner sketches and tentative specifications from the prior art for the purpose of evaluating obviousness under § 103, that error did not preclude the District Court from alternatively reaching its factual conclusions regarding those materials. The District Court specifically stated, [**23] in pertinent part, that "the 'X-Scanner' had to be dragged across the symbol rather than being aimed and shot." *17 U.S.P.Q.2d at 1747.*

The X-Scanner reference discloses a 2 lb. laser scanning head for reading bar code symbols at a maximum working range of 4" from the bar code. Thus, like the *'798* patent, the reference discloses a device capable of reading in a non-contact position. The disclosed device has a trigger, and may be used in either "portable mode" or "permanent mount mode." When operated in permanent mount mode, the device scans continuously from a fixed position above the bar code, much like the Verifier 315 already considered. The reference explains that the device, when operated in portable mode, has a "0-2 seconds scan duration" which is activated by a "trigger." In both modes, the laser beam puts out an "X" pattern and the "symbol must move across [the scanning] field, or vice versa."

In support of its conclusion that the X-Scanner had to be dragged across the symbol rather than aimed and shot, the District Court cited the expert testimony of Symbol's expert witness, Mr. Swartz. Swartz testified that the X-Scanner's "mode of use" was sufficiently different [**24] from the invention of the *'297* patent that it was "not a device that is used in a shoot mode, [] because it is, it creates an X-pattern as shown." Therefore, to obtain a reading, "you cannot do it stationary, you must have relative motion [between the symbol and device]." Swartz also stated "you would have to move [the scan head], you could not use it in aim and shoot mode." Opticon's evidence to the contrary failed to persuade the District Court, and Opticon has failed to persuade us that the District Court committed reversible error in crediting Symbol's evidence on this point.

[HN10] The obviousness inquiry conducted by the District Court correctly included review of the evidence offered on the objective indicia of nonobviousness, *Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538, 218 U.S.P.Q. (BNA) 871, 879 (Fed. Cir. 1983),* which included the failure of others to develop the claimed

invention and its commercial success. Nonobviousness is suggested by the failure of others to "find a solution to the problem which the patent[s] in question purport[] to solve. Such evidence [*1579] shows indirectly the presence of a significant defect [in the prior art], while serving [**25] as a simulated laboratory test of the obviousness of the solution to a skilled artisan." Note, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity, 112 U. Pa. L. Rev. 1169, 1173 (1964).* On this issue, the District Court found that Opticon's own expert witness, Mr. Collins, was "closely involved with the bar code industry since its inception and [] never conceived or developed an aim and shoot scanning device." *17 U.S.P.Q.2d at 1747.* The court further found that, despite years of effort, Opticon's technical witness, Mr. Knowles, was "never able to develop a scanner with the aim and shoot feature of the patents in suit." *Id.* Furthermore, as found by the District Court, Symbol's "aim and shoot" scanners have enjoyed tremendous commercial success, with about 200,000 devices sold for over $ 150,000,000 as of the time of trial. These findings are not challenged by Opticon.

In short, under the evidence that was put forward by Symbol and properly accepted by the court, the omitted reference adds nothing to the scope of the already considered prior art except a trigger in a bar code reader. This addition is minor, because the Carton Counter already [**26] discloses a trigger, although in a device for counting cartons. When the X-Scanner reference is considered with all the other references, the prior art as a whole still lacks a disclosure or suggestion of the "aim and shoot" feature, in which a laser beam sweeps laterally across the bar code while the hand-held device is held stationary and the target can be viewed.

We thus conclude that, even when the X-Scanner reference is included in the prior art, Opticon has not met its burden of proving that the inventions of the *'297* and *'186* patents would have been obvious under § 103. The District Court's error in alternatively excluding the X-Scanner reference from the prior art was therefore harmless.

B. *Double Patenting*

Opticon challenges the District Court's conclusion that the *'186* patent was not invalid for obviousness-type double patenting over the *'297* patent. After the examiner required restriction during prosecution of the *'297* patent, the applicants filed a divisional application containing method claims drawn to the invention of the originally non-elected Group VI claims. A continuation of the divisional containing both the old method and new apparatus claims eventually [**27] issued as the *'186* patent.

[HN11] With regard to double patenting, we recently explained that *35 U.S.C. § 121* (1988) n5 will not apply to remove the parent as a reference where the principle of consonance is violated:

> Consonance requires that the line of demarcation between the "independent and distinct inventions" that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement. Where that line is crossed the prohibition of the third sentence of Section 121 does not apply.

Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 688, 16 U.S.P.Q.2d (BNA) 1436, 1440 (Fed. Cir. 1990).

n5 Section 121 provides, in relevant part:

> [HN12] A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

[**28]

The corollary to this Court's statement in *Gerber Garment* is that [HN13] new or amended claims in a divisional application are entitled to the benefit of § 121 if the claims do not cross the line of demarcation drawn around the invention elected in the restriction requirement. If that line is crossed, the issue is whether the invention claimed in the *'186* patent would have been obvious in light of the invention claimed in the *'297* patent.

[*1580] Opticon contends, as it did before the trial court, that the appearance of "a whole *new* group of apparatus claims along with the method claims" in the

'186 patent proves that the claims "asserted against Opticon are drawn to the elected species of the *'297* patent and not the species upon which the divisional was filed." We read Opticon's bare assertions in its opening brief, without record citation, to allege that because the Group VI invention was described as a "method" in the restriction requirement, the added *apparatus* claims fail to comply with the requirement. The District Court had before it the declaration of Mr. Berger, which fully supports a conclusion that both the method and apparatus claims are directed to the Group VI invention. [**29] Berger stated that the Group VI invention is a system of scanner plus decoder, with a means for stopping the scanner after the symbol is successfully decoded. Therefore, whether method or apparatus, all the *'186* patent claims are drawn to that system. Berger further asserted that [HN14] in the electronic arts, the Patent and Trademark Office (PTO) has not restricted between claims to an apparatus and to a method of using the apparatus. *Cf. Studiengesellschaft Kohle v. Northern Petrochemical Co., 784 F.2d 351, 354, 228 U.S.P.Q. (BNA) 837, 840 (Fed. Cir. 1986), cert. dismissed, 478 U.S. 1028, 92 L. Ed. 2d 763, 106 S. Ct. 3343 (1986)* (chemical composition claims defined invention different from process claims). In short, Berger explained that the word "method" in the description of Group VI during restriction did not mean that the *claims* were limited to a method, but was merely a short-hand description of the invented *system*. For support, Berger stated that the examiner collectively characterized the method and apparatus claims of another non-elected group, Group IV, as a "method." Finally, Berger noted that the examiner's statement that "the Group I invention does not require [**30] the particular *apparatus* of Group . . . VI," (emphasis added) cannot be reconciled with Opticon's argument that the invention of Group VI could only be expressed as a method. In light of this testimony, we cannot agree that a breach of the restriction requirement occurred. The safeguard of § 121 therefore applies in this case, and the *'297* patent is not available as a reference against the *'186* patent.

Furthermore, even if there had been a breach of the restriction requirement, we would reject Opticon's argument on the ultimate obviousness-type double patenting inquiry: whether the claims of the *'186* patent are patentably distinct from the claims of the *'297* patent. *See In re Borah, 53 C.C.P.A. 800, 354 F.2d 1009, 1017, 148 U.S.P.Q. (BNA) 213, 220 (CCPA 1966)* [HN15] (crux of obviousness-type double patenting inquiry lies in comparison of claims); *see also Gerber Garment, 916 F.2d at 686, 16 U.S.P.Q.2d at 1438* (judicially created doctrine of obviousness-type double patenting applies when two applications or patents, not drawn to precisely the same invention, are "drawn to inventions so very much alike as to render one obvious in view of the other and to [**31] effectively extend the life of the patent that would have the earlier of the two issue dates").

[HN16] Double patenting is an affirmative defense. *Studiengesellschaft Kohle v. Northern Petrochemical Co., 784 F.2d at 352, 228 U.S.P.Q. at 838.* Opticon was therefore required to prove double patenting by clear and convincing evidence, a heavy and unshifting burden. *RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 U.S.P.Q. (BNA) 385, 387 (Fed. Cir. 1984)* (invalidity requires clear and convincing proof, and burden remains at all times with patent challenger); *Carman Indus., Inc. v. Wahl, 724 F.2d 932, 940, 220 U.S.P.Q. (BNA) 481, 487 (Fed. Cir. 1983)* ("there is a heavy burden of proof on one seeking to show double patenting").

Opticon's conclusory allegation that the District Court's decision on double patenting was in error, without citation to the record, the patents or the testimony of the witnesses, does not support reversal. *See In re Mulder, 716 F.2d 1542, 1550, 219 U.S.P.Q. (BNA) 189, 197 (Fed. Cir. 1983)* (to [HN17] obtain reversal, appellant must clearly explain why decision below [**32] is wrong). As a court of review, it is not our function to search the voluminous trial record, prosecution histories, and patents to fashion a substantive [*1581] basis for Opticon's argument. *See Preemption Devices, Inc. v. Minnesota Mining & Mfg. Co., 732 F.2d 903, 905, 221 U.S.P.Q. (BNA) 841, 842 (Fed. Cir. 1984)* (as appellate court, it is not our function to search the record in order to reach a conclusion favoring appellant).

Nevertheless, even a brief review of the *'297* patent reveals that all of the asserted claims are directed to a laser self-scanning head with a "trigger," a "handle," and means for "sighting the symbol along a direct line of sight." In contrast, the asserted claims of the *'186* patent recite additional features. Although the claims of the *'186* patent cover a laser scanning system that includes a portable laser scanning head, the system also includes means for *repetitively* self scanning a bar code symbol until it is decoded. Furthermore, when successful decoding has been achieved, the system alerts the user and automatically stops scanning. The repetitive scan feature adds the advantage of increasing the accuracy of decoding. Claim 8 includes [**33] a further feature of terminating the repetitive scan if no successful decode is achieved within a set time period.

Opticon contends in its reply brief that the automatic termination feature is merely an obvious addition to the invention claimed in the *'297* patent, because its expert testified that this feature "is a software program, essentially a software program, or firmware program, if you go back far enough in time." The mere reference to "a software program" does not demonstrate that the

program would have been obvious or that its addition to the invention of the *'297* patent would have been obvious.

Furthermore, the policy behind the double patenting doctrine, the prevention of unlawful extension of the patent grant, does not favor Opticon's position. Although the *'297* patent will expire before the *'186* patent, the *'186* patent will not "extend" the property right conveyed in the *'297* patent. *See Gerber Garment, 916 F.2d at 686, 16 U.S.P.Q.2d at 1438* (obviousness-type double patenting occurs when a second patent would "effectively extend the life of the patent that would have the earlier of the two issue dates"). Since the *'186* patent is not infringed [**34] by practice of the invention claimed in the *'297* patent, the world will be free to use the invention of the *'297* patent once it expires. *See In re Kaplan, 789 F.2d 1574, 1578, 229 U.S.P.Q. (BNA) 678, 681-82 (Fed. Cir. 1986)* (no double patenting found where no extension of patent right is possible because when the first to issue patent expires, "the world will be free to use" the first patented invention so long as the second patented invention is not used in it).

Finally, Opticon contends that the judgment of the District Court should be reversed for failure to state findings of fact under Fed. R. Civ. P. 52(a). On appeal, Opticon raises the issue of consonance. As this Court explained in *Gerber Garment*, [HN18] "the presence or absence of consonance will necessarily depend upon analysis of the involved claims," *916 F.2d at 688, 16 U.S.P.Q.2d at 1441*, which are construed as a matter of law. *Cf. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 n.3, 227 U.S.P.Q. (BNA) 543, 547 n.3 (Fed. Cir. 1985)* ("Under this court's precedent substantial identity between claims, a matter of claim interpretation, is a question [**35] of law."). In connection with construing claims, we are free to examine the prosecution history on appeal even where the trial court erroneously fails to consider it. *See Lemelson v. United States, 752 F.2d 1538, 1550, 224 U.S.P.Q. (BNA) 526, 532-33 (Fed. Cir. 1985)*. This is particularly so where, as here, there are no underlying findings of fact required for such construction. Because we have concluded that the claims of the *'186* patent are within the subject matter of Group VI as a matter of law, the absence of Rule 52(a) findings of fact on this issue is not reversible error.

We thus conclude that Opticon has failed to demonstrate that the District Court erred in finding that no claim in the *'186* patent was proved invalid for double patenting.

IV. ENFORCEABILITY

Opticon challenges the District Court's conclusion that neither the *'297* patent [*1582] nor the *'186* patent are unenforceable because of inequitable conduct during prosecution. Opticon reiterates its argument, considered and rejected below, that Symbol fraudulently withheld information from the examiner concerning the Verifier 315 and the Laserscan during prosecution of the *'297* and *'186* patents.

Opticon asserts [**36] that the District Court erroneously failed to consider references that Symbol "should have known" were material, citing *FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415, 5 U.S.P.Q.2d (BNA) 1112, 1116 (Fed. Cir. 1987)*. However, we have repeatedly rejected the simple negligence standard that Opticon urges us to adopt. *See, e.g., Jaskiewicz v. Mossinghoff, 822 F.2d 1053, 1058, 3 U.S.P.Q.2d (BNA) 1294, 1299 (Fed. Cir. 1987)* ("mere negligence is not sufficient to infer fraud or dishonesty"). Moreover, even [HN19] a finding of gross negligence:

> does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.

Kingsdown Medical Consultants v. Hollister Inc., 863 F.2d 867, 876, 9 U.S.P.Q.2d (BNA) 1384, 1392 (Fed. Cir. 1988), cert. denied, 490 U.S. 1067, 104 L. Ed. 2d 633, 109 S. Ct. 2068 (1989).

Opticon asserts that a flyer submitted by Symbol during reexamination depicted an operational Verifier 315, and that Symbol deceived the PTO by indicating that the flyer [**37] depicted only an empty shell or housing. The record is replete with evidence supporting a conclusion that, at the very least, Symbol possessed a good faith belief that the photograph in the flyer indeed depicted only an empty shell of an inoperable device, a belief to which the District Court, in the final analysis, itself concurred. Opticon further argues that Symbol improperly withheld from the examiner information relating to the Laserscan device during prosecution of its patents, but as noted *supra*, that device was a modified version of the Laserchek device disclosed in the *'798* patent. We conclude that the reference was merely cumulative to the teachings of the *'798* patent, imparting no obligation to disclose. *See J.P. Stevens & Co. v. Lex Tex, Ltd., 747 F.2d 1553, 223 U.S.P.Q. (BNA) 1089, 1092 (Fed. Cir. 1984), cert. denied, 474 U.S. 822, 88 L. Ed. 2d 60, 106 S. Ct. 73 (1985)* ("[a] reference that would have been merely cumulative is not material").

We find no abuse of discretion in the District Court's conclusion that the *'297* and *'186* patents were not proved unenforceable for inequitable conduct during prosecution.

V. CONCLUSION

Among other issues, Opticon alleges [**38] that the sparseness of the District Court's Rule 52 findings, particularly on infringement and double patenting, preclude effective appellate review. Our opinion amply demonstrates the absence of merit in that allegation. Having duly considered and rejected each of Opticon's other arguments, we affirm the judgment of the District Court.

AFFIRMED.

APPENDIX

The '297 Patent

1. In a laser scanning system for reading bar code symbols, a light-weight easy-to-manipulate laser scanning head normally supportable only by a user throughout the reading of the symbols, comprising:

(a) a housing having wall portions bounding an outlet port and bounding an interior space whose volume measures less than a value which is on the order of 100 cubic inches;

(b) a light source mounted in the interior space of the housing for generating a laser light beam;

(c) miniature optic means mounted in the interior space of the housing for directing the laser light beam along a light path through the outlet port and towards a bar code symbol which is located exteriorly of the housing by a distance sufficient to permit the user to conveniently register the laser light beam on the symbol by sighting the symbol [**39] along a direct line of sight which does not pass through the housing;

[*1583] (d) miniature scanning means mounted in the light path and in the interior space of the housing for cyclically sweeping the laser light beam across the bar code symbol for reflection therefrom;

(e) miniature sensor means mounted in the interior space of the housing for detecting the intensity of light reflected from the bar code symbol, and for generating an electrical signal indicative of the detected intensity of the reflected light;

(f) miniature signal processing means mounted in the interior space of the housing for processing the electrical signal to generate therefrom data descriptive of the bar code symbol;

(g) all of said light source, optic means, sensor means and signal processing means together with said housing comprising the light-weight laser scanning head whose total weight measures less than a value which is on the order of two pounds;

(h) handle means for normally supporting the light-weight laser scanning head in non-contacting relationship with the symbol during reading thereof; and

(i) manually actuatable trigger means on the housing for initiating reading of the symbol each time the trigger [**40] means is manually actuated by the user.

The '186 Patent

1. A laser scanning system for reading bar code symbols, each in its respective turn, comprising:

(a) a light-weight, hand-held head normally supportable by a user in a normally non-contacting relationship with the symbols during reading thereof, said head including therein

(i) means for generating a laser beam, and for directing the same along a light path through an outlet port of the head to each symbol,

(ii) scanning means for repetitively scanning the directed laser beam across each symbol for reflection therefrom,

(iii) sensor means for detecting the variable intensity of each scanned laser beam reflected from each symbol, and for generating an electrical signal indicative of the detected intensity for each symbol, and

(iv) signal processing means for processing each electrical signal, and for generating a processed electrical signal for each symbol;

(b) decoding means operatively associated with the signal processing means, for decoding the processed signal for each symbol to be read;

(c) manually actuatable trigger means on the head and operatively associated with the decoding means, for initiating reading of each [**41] symbol upon each manual actuation of the trigger means from one state to another state by the user; and

(d) means operatively associated with the decoding means, for determining a successful decoding of each symbol, and for non-manually terminating the reading of each symbol upon the determination of the successful decoding thereof.

* * *

11. A method of successively sensing and reading bar code symbols, each in its respective turn, comprising the steps of:

(a) generating a laser beam, and directing the same along a light path to each symbol;

(b) repetitively scanning the directed laser beam across each symbol for reflection therefrom;

(c) detecting the variable intensity of each scanned laser beam reflected from each symbol, and generating an electrical signal indicative of the detected intensity for each symbol;

(d) processing each electrical signal, and generating a processed electrical signal for each symbol;

(e) performing steps (a), (b), (c) and (d) in a light-weight, hand-held head, and normally supporting the same by a user in a normally non-contacting relationship with the symbols during reading thereof;

(f) decoding the processed signal for each symbol to be read;

(g) initiating [**42] reading of each symbol upon each manual actuation from one state [*1584] to another state of a trigger by the user; and

(h) determining a successful decoding of each symbol, and non-manually terminating the reading of each symbol upon the determination of the successful decoding thereof.

The '470 Patent

1. In a scanning system for reading bar code symbols, a scanning head comprising:

(a) a housing having an elongated body portion including a front region, a rear region, and an intermediate body region extending between the front and rear regions, and having side walls spaced transversely apart of each other by a predetermined width;

(b) light source means mounted within the housing, for generating an incident light beam;

(c) optic means mounted within the housing, for directing the incident beam along a light path towards a reference plane located exteriorly of the housing in the vicinity of the front region thereof, and towards a bar code symbol located in the vicinity of the reference plane to thereby generate a reflected light beam which is directed along a light path away from the reference plane and back towards the housing;

(d) scanning means mounted within the housing at the rear [**43] region thereof, for sweeping at least one of said beams over a field of view across the bar code symbol;

(e) sensor means mounted within the housing, for detecting the light intensity in the reflected beam over a field of view across the bar code symbol, and for generating an electrical signal indicative of the detected light intensity;

(f) signal processing means mounted within the housing, for processing the electrical signal to generate therefrom data descriptive of the bar code symbol; and

(g) window means mounted on the housing, and having a light-transmissive window at the rear region in close adjacent confronting relationship with the scanning means thereat, said window being configured and positioned in the light path of said at least one swept beam to permit the latter to pass through the window and unobstructedly travel exteriorly of and past the front and intermediate body regions of the housing,

> whereby the field of view of the swept beam is substantially independent of the predetermined width of the housing due to its exterior transmission outside of the front and intermediate body regions of the housing.

LEXSEE

In Re Dow Chemical Co.

No. 87-1406

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

837 F.2d 469; 1988 U.S. App. LEXIS 587; 5 U.S.P.Q.2D (BNA) 1529

January 25, 1988, Decided

PRIOR HISTORY: [**1]

Appealed from: United States Patent and Trademark Office Board of Patent Appeals and Interferences.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant challenged the order of the United States Patent and Trademark Office Board of Patent Appeals and Interferences, rejecting on reexamination all claims of appellant's patent application.

OVERVIEW: Appellant challenged the order of the appeals board rejecting all the claims of appellant's patent application, which based its decision on the contention that the claimed invention would have been obvious in terms of *35 U.S.C.S § 103.* Appellant argued that the board erred when it engaged in hindsight reconstruction of the claimed invention and combined prior art teachings when no reference showed or suggested that references should or could be combined successfully. The court found that the evidence as a whole did not support the board's conclusion that the claimed invention would have been obvious in terms of *35 U.S.C.S. § 103,* and that the board applied an incorrect "obvious to experiment" standard to its determination.

OUTCOME: The court reversed the board's rejection of appellant's patent application because it found that the evidence as a whole did not support the board's conclusion that the claimed invention would have been obvious, and the board applied an incorrect "obvious to experiment" standard to its determination.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN1] Recognition of need, and difficulties encountered by those skilled in the field, are classical indicia of unobviousness.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN2] The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN3] In determining whether a suggestion of obviousness can fairly be gleaned from the prior art, the full field of the invention must be considered, for the person of ordinary skill is charged with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN4] The skepticism of an expert, expressed before inventors proved him wrong, is entitled to fair evidentiary weight.

COUNSEL:

Douglas N. Deline, The Dow Chemical Co., argued for Appellant. With him on the brief was Bernd W. Sandt.

John H. Raubitschek, Associate Solicitor, Office of the Solicitor, argued for Appellee. With him on the brief were Joseph F. Nakamura, Solicitor and Fred E. McKelvey, Deputy Solicitor.

JUDGES:

Smith, Nies, and Newman, Circuit Judges.

OPINIONBY:

NEWMAN

OPINION:

[*470] NEWMAN, Circuit Judge.

Dow Chemical Company appeals the decisions of the United States Patent and Trademark Office Board of Patent Appeals and Interferences, No. 86-3426 (Feb. 25, 1987) and No. 662-81 (Mar. 25, 1986), together rejecting all the claims on reexamination of United States Patent No. *3,919,354* entitled "Impact Resistant Polymers of a Resinous Copolymer of an Alkenyl Aromatic Monomer and an Unsaturated Dicarboxylic Anhydride.". We reverse.

The Rejection

The invention is an impact resistant rubber-based resin having improved resistance to heat distortion. Claim 28, the broadest claim on appeal, is illustrative:

> 28. A polymer suitable for molding and extrusion, of substantially [**2] improved resistance to mechanical shock and impact, the polymer consisting essentially of the polymerization product of
>
> a. a monovinyl alkenyl aromatic monomer containing up to 12 carbon atoms and having the alkenyl group attached directly to the benzene nucleus, the alkenyl aromatic compound being present in a proportion of from about 65 to 95 parts by weight and from 35 to 5 parts by weight of an unsaturated dicarboxylic acid anhyride readily copolymerizable therewith, and
>
> b. from 5 to 35 parts by weight of a diene rubber per 100 parts of (a) plus (b), the rubber consisting essentially of 65 to 100 weight percent butadiene, or isoprene and up to 35 weight percent of an alkenyl aromatic hydrocarbon as the sole other monomer in the rubber, the rubber having a glass temperature not higher than 0 degrees C., the rubber being in the form of a plurality of particles having diameters within the range of 0.02 to 30 microns dispersed throughout a matrix of polymer of alkenyl aromatic monomer and the anhydride, at least a major portion of the rubber particles containing distinct occlusions of the polymer of (a), with the further limitation that
>
> the polymer of (a) is a nonequimolar [**3] random copolymer.

[*471] The preferred ingredients are styrene, maleic anhydride, and synthetic diene rubbers, and our discussion will be in these terms, as was the Board's.

The Board's decision that the claimed invention would have been obvious in terms of *35 U.S.C. § 103* was based on the combination of two references: a 1966 article by Molau and Keskkula entitled "Heterogeneous Polymer Systems IV. Mechanism of Rubber Particle Formation in Rubber-Modified Vinyl Polymers", and Baer U.S. Patent No. *2,971,939*. Also discussed were Farmer U.S. Patent No. *2,275,951* and a publication by Bacon and Farmer entitled "The Interaction of Maleic Anhydride with Rubber", although the Board stated that the rejection was sustainable without relying on either of these references.

The Prior Art

The Molau/Keskkula article shows the preparation of a resin having high impact strength by dissolving synthetic diene rubber in styrene and polymerizing the styrene. This reference teaches that phase inversion is necessary to the formation of these moldable, extrudable resins. Baer prepares nonequimolar random maleic anhydride-styrene copolymers by a technique [**4] whose salient feature is adding the maleic anhydride slowly to polymerizing styrene under controlled conditions.

Farmer shows the reaction among natural rubber, styrene, and maleic anhydride, and also states that maleic anhydride reacts directly with the rubber. The Bacon and Farmer article also shows the reaction of maleic anhydride with natural rubber. These products, according to Dow's evidence and as found by the Board, do not have a dispersed rubber phase containing occlusions, and are not moldable.

Dow argues that the Board has engaged in hindsight reconstruction of the claimed invention. To support its position Dow refers to several scientific publications and other references, in addition to those cited by the PTO, and evidence submitted by declaration and deposition.

The first group of references to which Dow refers shows the reaction of maleic anhydride with natural or synthetic rubbers. These references show both intermolecular and intramolecular reactions between maleic anhydride and the various rubbers, but not a grafted rubber, which is said by Dow to characterize its product. Additional references are cited by Dow to show that maleic anhydride is much more reactive [**5] with diene-type synthetic rubbers than with natural rubber, and that the reaction with the synthetic rubbers is difficult to control and the product is unpredictable.

Another reference cited by Dow, the *Encyclopedia of Science and Technology*, states the general rule, derived from experience with acrylonitrile, that copolymers with synthetic diene rubbers have elevated glass transition temperatures; Dow advises that this is a highly undesirable property for a high-impact strength resin.

Another series of references cited by Dow shows several known techniques of reacting styrene and maleic anhydride to prepare nonequimolar copolymers, all different from the technique shown in the Baer patent.

Analysis

The Board held that the claimed product results from the application of the Baer technique to a styrene-maleic anhydride polymer system which includes synthetic diene rubber, and that it would have been obvious to do that which these inventors did if one wanted to increase the heat stability of a known high impact styrene rubber resin.

The crux of Dow's argument is that no reference shows or suggests that these references should or could be combined successfully. Indeed, [**6] the Board agreed, stating that "it is not apparent from the evidence whether rubber and maleic anhydride would have been expected to react *in the process suggested by the combined disclosure of Molau and Baer* . . . ." (Emphasis in original).

Dow also points out, referring to the Keskkula evidence, that it was believed that these products could not be made by [*472] the mass polymerization techniques of the prior art. Dow asserts that no reference, including Baer, suggested that the Baer technique could produce the requisite phase inversion in a system containing diene rubber, and could produce a diene-rubber containing resin that could be molded and had the other desired high-impact and thermal properties.

Dow refers to the Farmer patent, cited by the examiner and the Board, which shows that the reaction of styrene, maleic anhydride, and natural rubber forms a product that is unsuitable as a molding resin. Dow argues that Farmer leads away from the Dow invention, in that Farmer obtains precisely the "runaway" reaction, and undesirable product, that Keskkula believed was characteristic of reactions involving styrene, maleic anhydride, and rubbers. Dow points to Dr. Keskkula's [**7] Report to Dow management, written in 1966 at about the time the present invention was made, pointing out the many problems in attempting to produce the three-component product that these inventors later succeeded in producing.

In response, the Commissioner argues that even though an expert polymer scientist, Dr. Keskkula, "personally may have been surprised by the invention at the time it was made, it does not necessarily follow that the invention would have been unobvious to one of ordinary skill in the art." The Commissioner suggests that one less encumbered by knowledge of the need for phase inversion, as described in the Molau/Keskkula article, might have achieved the Dow product by combining the references in the way suggested by the Commissioner. Reflecting on this theory of invention, we observe that such a person did not do so, despite the decades of experimentation with these components, and the recognition of need, as evidenced by the many references cited by both sides. *See In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984).* [**8]

The Board held that Dow's statement in the patent specification that it was known that styrene/maleic anhydride copolymers had improved heat resistance as compared with styrene rubbers, made it prima facie obvious to combine these three components. Indeed, the record shows that such combinations had previously been made, in various ways, but without producing the product here desired. That there were other attempts, and various combinations and procedures tried in the past, does not render obvious the later successful one. The PTO's reliance on Dow's "admission" of longfelt need as prima facie evidence of obviousness is contrary to logic as well as law. [HN1] Recognition of need, and difficulties encountered by those skilled in the field, are classical indicia of unobviousness. *Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966); Custom Accessories v. Jeffrey-Allan Industries, 807 F.2d 955, 960, 1 USPQ2d 1196, 1199 (Fed. Cir. 1986).* Further, a patent applicant's statement of the purpose of the work is not prior [**9] art.

The Board thus concluded that although one would not know in advance whether the Baer technique would work at all in the presence of diene rubber, or produce a moldable high-impact product, if it did succeed it would have been obvious. The Board criticized Keskkula's evidence for not stating whether, after these inventors proposed the procedure here at issue, Keskkula would have expected the maleic anhydride to react preferentially with the diene rubber or with the styrene and to what effect on the impact properties of the product. The PTO argues that unless the prior art is shown to have led one of ordinary skill to expect the Baer technique to fail, the applicant's burden is not met. This is not the criterion. That these inventors eventually succeeded when they and others had failed does not mean that they or their colleagues must have expected each new idea to fail. Most technological advance is the fruit of methodical, persistent investigation, as is recognized in *35 U.S.C. § 103* ("Patentability shall not be negatived by the manner in which the invention was made").

[*473] [HN2] [**10] The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. *See Burlington Industries v. Quigg, 822 F.2d 1581, 1583, 3 USPQ2d 1436, 1438 (Fed. Cir. 1987); In re Hedges, 783 F.2d 1038, 1041, 228 USPQ 685, 687 (Fed. Cir. 1986); Orthopedic Equipment Co. v. United States, 702 F.2d 1005, 1013, 217 USPQ 193, 200 (Fed. Cir. 1983); In re Rinehart, 531 F.2d 1048, 1053-54, 189 USPQ 143, 148 (CCPA 1976).* Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure.

[HN3] In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered; for the person of ordinary skill is charged with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention. The [**11] Commissioner argues that since the PTO is no longer relying on Farmer or the Bacon and Farmer article, the applicant is creating a "straw man". It is indeed pertinent that these references teach against the present invention. Evidence that supports, rather than negates, patentability must be fairly considered.

The PTO presents, in essence, an "obvious to experiment" standard for obviousness. However, selective hindsight is no more applicable to the design of experiments than it is to the combination of prior art teachings. There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure. *Interconnect Planning Corporation v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985).* Of the many scientific publications cited by both Dow and the PTO, none suggests that any process could be used successfully in this three-component system, to produce this product having the desired properties. [HN4] The skepticism of an expert, expressed before these inventors proved him wrong, is entitled to fair [**12] evidentiary weight, *see In re Piasecki, 745 F.2d 1468, 1475, 223 USPQ 785, 790 (Fed. Cir. 1984); In re Zeidler, 682 F.2d 961, 966, 215 USPQ 490, 494 (CCPA 1982),* as are the five to six years of research that preceded the claimed invention. The evidence as a whole does not support the PTO's conclusion that the claimed invention would have been obvious in terms of *35 U.S.C. § 103.*

REVERSED.

LEXSEE

IN RE PATRICK H. O'FARRELL, BARRY A. POLISKY and DAVID H. GELFAND

No. 87-1486

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

853 F.2d 894; 1988 U.S. App. LEXIS 10951; 7 U.S.P.Q.2D (BNA) 1673

August 10, 1988, Decided

PRIOR HISTORY: [**1]

Appealed from: U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellants sought review of the decision of U.S. Patent and Trademark Office Board of Patent Appeals and Interferences rejecting appellants' application under *35 U.S.C.S. § 103* because the claimed invention was obvious at the time the invention was made in view of a published paper by two of the coinventors.

OVERVIEW: Appellants alleged that at the time their article was published there was significant unpredictability in the field of molecular biology so that the article would not have rendered the claimed method of translating heterologous DNA in bacteria obvious to one of ordinary skill in the art. In the alternative, appellants argued that the rejection was founded on the impermissible "obvious to try" standard. The court disagreed, holding that in light of the article, the claimed invention would have been obvious within the meaning of *35 U.S.C.S. § 103*. The article contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful. Appellants foreclosed themselves from obtaining a patent because they published their pioneering studies more than a year before applying for a patent.

OUTCOME: The decision rejecting appellants' patent application was affirmed because the claimed invention was obvious in light of the published paper by two of the three co-inventors prior to filing their patent application.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN1] See *35 U.S.C.S. § 103*.

Civil Procedure > Trials > Bench TrialsPatent Law > Nonobviousness > Tests & Proof of Obviousness
[HN2] Obviousness under *35 U.S.C.S. § 103* is a question of law.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN3] An analysis of obviousness must be based on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN4] Keeping the four statutory factors in mind and considering all of the evidence, the court must determine the correctness of the board's legal determination that the claimed invention as a whole would have been obvious to a person having ordinary skill in the art at the time the invention was made.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN5] Obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious.

COUNSEL:

J. Bruce McCubbrey, Fitch, Even, Tabin & Flannery, of San Francisco, California, argued for Appellant. Virginia H. Meyer, Fitch, Even, Tabin & Flannery, of San Francisco, California, was on the brief for Appellant.

Harris A. Pitlick, Associate Solicitor, of Arlington, Virginia, argued for Appellee. With him on the brief were Joseph F. Nakamura, Solicitor and Fred E. McKelvey, Deputy Solicitor.

JUDGES:

Markey, Chief Judge, Rich and Nies, Circuit Judges.

OPINIONBY:

RICH

OPINION:

[*895] RICH, Circuit Judge.

This appeal is from the decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences (board) affirming the patent examiner's final rejection of patent application Serial No. 180,424, entitled "Method and Hybrid Vector for Regulating Translation of Heterologous DNA in Bacteria." The application was rejected under *35 U.S.C. § 103* on the ground that the claimed invention would have been obvious at the time the invention was made in view of a published paper by two of the three coinventors, and a publication by Bahl, [**2] Marians & Wu, 1 *Gene* 81 (1976) (Bahl). We affirm.

The claimed invention is from the developing new field of genetic engineering. A broad claim on appeal reads:

> Claim 1. A method for producing a predetermined protein in a stable form in a transformed host species of bacteria comprising, providing a cloning vector which includes at least a substantial portion of a gene which is indigenous to the host species of bacteria and is functionally transcribed and translated in that species, said substantial portion of said indigenous gene further including the regulatory DNA sequences for RNA synthesis and protein synthesis but lacking the normal gene termination signal, and linking a natural or synthetic heterologous gene encoding said predetermined protein to said indigenous gene portion at its distal end, said heterologous gene being in proper orientation and having codons arranged in the same reading frame as the codons of said indigenous gene portion so that readthrough can occur from said indigenous gene portion into said heterologous gene in the same reading frame, said heterologous gene portion further containing sufficient DNA sequences to result in expression of a fused [**3] protein having sufficient size so as to confer stability on said predetermined protein when said vector is used to transform said host species of bacteria.

Illustrative embodiments are defined in more specific claims. For example:

> Claim 2. A method for producing a predetermined protein in a stable form in a transformed host species of bacteria, comprising, providing an *E. coli* plasmid having an operator, a promoter, a site for the initiation of translation, and at least a substantial portion of the beta-galactosidase gene of the *E. coli* lactose operon, said substantial portion of said beta-galactosidase gene being under the control of said operator, promoter and site for initiation of translation, said substantial portion of said beta-galactosidase gene lacking the normal gene termination signal, and linking a heterologous gene encoding said predetermined protein to said beta-galactosidase gene portion at its distal end, said heterologous gene being in proper orientation and having codons arranged in the same reading frame as the codons of the said beta-galactosidase gene portion so that readthrough can occur

from said beta-galactosidase gene portion into said [**4] heterologous gene in the same reading frame, said heterologous gene portion further containing sufficient DNA sequences to result in expression of a fused protein having sufficient size so as to confer stability on said predetermined protein when said vector is used to transform said host species of bacteria.

Claim 3. The method of Claim 2 wherein said *E. coli* plasmid comprises the plasmid designated pBGP120.

Although the terms in these claims would be familiar to those of ordinary skill in genetic engineering, they employ a bewildering vocabulary new to those who are not versed in molecular biology. An understanding of the science and technology on which these claims are based is essential before one can analyze and explain whether the claimed invention would have been obvious in light of the prior art.

I. *Background* n1

n1 Basic background information about molecular biology and genetic engineering, can be found in Alberts, Bray, Lewis, Raff, Roberts & Watson, *The Molecular Biology of the Cell*, 1-253, 385-481 (1983) [hereinafter *The Cell*]; Watson, Hopkins, Roberts, Steitz & Weiner, *The Molecular Biology of the Gene*, Vol. 1 (4th ed., 1987) 3-502 [hereinafter *The Gene*]. These standard textbooks were used to supplement the information in the glossary supplied by appellants. The description here is necessarily simplified and omits important facts and concepts that are not necessary for the analysis of this case.

[**5]

Proteins are biological molecules of enormous importance. Proteins include enzymes [*896] that catalyze biochemical reactions, major structural materials of the animal body, and many hormones. Numerous patents and applications for patents in the field of biotechnology involve specific proteins or methods for making and using proteins. Many valuable proteins occur in nature only in minute quantities, or are difficult to purify from natural sources. Therefore, a goal of many biotechnology projects, including appellants' claimed invention, is to devise methods to synthesize useful quantities of specific proteins by controlling the mechanism by which living cells make proteins.

The basic organization of all proteins is the same. Proteins are large polymeric molecules consisting of chains of smaller building blocks, called *amino acids*, that are linked together covalently. n2 The chemical bonds linking amino acids together are called *peptide* bonds, so proteins are also called *polypeptides*. n3 It is the exact sequence in which the amino acids are strung together in a polypeptide chain that determines the identity of a protein and its chemical characteristics. n4 Although [**6] there are only 20 amino acids, they are strung together in different orders to produce the hundreds of thousands of proteins found in nature.

n2 There are twenty amino acids: alanine, valine, leucine, isoleucine, proline, phenylalanine, methionine, tryptophan, glycine, asparagine, glutamine, cysteine, serine, threonine, tyrosine, aspartic acid, glutamic acid, lysine, arginine, and histidine.

n3 Proteins are often loosely called *peptides*, but technically proteins are only the larger peptides with chains of at least 50 amino acids, and more typically hundreds of amino acids. Some proteins consist of several polypeptide chains bound together covalently or noncovalently. The term "peptide" is broader than "protein" and also includes small chains of amino acids linked by peptide bonds, some as small as two amino acids. Certain small peptides have commercial or medical significance.

n4 Polypeptide chains fold up into complex 3-dimensional shapes. It is the shape that actually determines many chemical properties of the protein. However, the configuration of a protein molecule is determined by its amino acid sequence. *The Cell* at 111-12; *The Gene* at 50-54.

[**7]

To make a protein molecule, a cell needs information about the sequence in which the amino acids must be assembled. The cell uses a long polymeric molecule, DNA (deoxyriboneucleic acid), to store this information. The subunits of the DNA chain are called *nucleotides*. A nucleotide consists of a nitrogen-containing ring compound (called a *base*) linked to a 5-carbon sugar that has a phosphate group attached. n5 DNA is composed of only four nucleotides. They differ from each other in the base region of the molecule. The four bases of these subunits are adenine, guanine, cytosine, and thymine (abbreviated respectively as A, G, C and T). The sequence of these bases along the DNA molecule specifies which amino acids will be inserted in sequence into the polypeptide chain of a protein.

n5 The sugar in DNA is deoxyribose, while the sugar in RNA, *infra*, is ribose. The sugar and phosphate groups are linked covalently to those of adjacent nucleotides to form the backbone of the long unbranched DNA molecule. The bases project from the chain, and serve as the "alphabet" of the genetic code.

DNA molecules actually consist of two chains tightly entwined as a double helix. The chains are not identical but instead are complementary: each A on one chain is paired with a T on the other chain, and each C has a corresponding G. The chains are held together by noncovalent bonds between these complementary bases. This double helical structure plays an essential role in the replication of DNA and the transmission of genetic information. *See generally The Cell* at 98-106; *The Gene* at 65-79. However, the information of only one strand is used for directing protein synthesis, and it is not necessary to discuss the implication of the double-stranded structure of DNA here. RNA molecules, *infra*, are single stranded.

[**8]

DNA molecules do not participate directly in the synthesis of proteins. DNA acts as a permanent "blueprint" of all of the [*897] genetic information in the cell, and exists mainly in extremely long strands (called *chromosomes*) containing information coding for the sequences of many proteins, most of which are not being synthesized at any particular moment. The region of DNA on the chromosome that codes for the sequence of a single polypeptide is called a *gene*. n6 In order to *express* a gene (the process whereby the information in a gene is used to synthesize new protein), a copy of the gene is first made as a molecule of RNA (ribonucleic acid).

n6 Chromosomes also contain regions of DNA that are not part of genes, i.e., do not code for the sequence of amino acids in proteins. These include sections of DNA adjacent to genes that are involved in the control of transcription, *infra*, and regions of unknown function.

RNA is a molecule that closely resembles DNA. It differs, however, in that [**9] it contains a different sugar (ribose instead of deoxyribose) and the base thymine (T) of DNA is replaced in RNA by the structurally similar base, uracil (U). Making an RNA copy of DNA is called *transcription*. The transcribed RNA copy contains sequences of A, U, C, and G that carry the same information as the sequence of A, T, C, and G in the DNA. That RNA molecule, called *messenger RNA*, then moves to a location in the cell where proteins are synthesized.

The code whereby a sequence of nucleotides along an RNA molecule is translated into a sequence of amino acids in a protein (i.e., the "genetic code") is based on serially reading groups of three adjacent nucleotides. Each combination of three adjacent nucleotides, called a *codon*, specifies a particular amino acid. For example, the codon U-G-G in a messenger RNA molecule specifies that there will be a tryptophan molecule in the corresponding location in the corresponding polypeptide. The four bases A, G, C and U can be combined as triplets in 64 different ways, but there are only 20 amino acids to be coded. Thus, most amino acids are coded for by more than one codon. For example, both U-A-U and U-A-C code for tyrosine, [**10] and there are six different codons that code for leucine. There are also three codons that do not code for any amino acid (namely, U-A-A, U-G-A, and U-A-G). Like periods at the end of a sentence, these sequences signal the end of the polypeptide chain, and they are therefore called *stop codons*.

The cellular machinery involved in synthesizing proteins is quite complicated, and centers around large structures called *ribosomes* that bind to the messenger RNA. The ribosomes and associated molecules "read" the information in the messenger RNA molecule, literally shifting along the strand of RNA three nucleotides at a time, adding the amino acid specified by that codon to a growing polypeptide chain that is also attached to the ribosome. When a stop codon is reached, the polypeptide chain is complete and detaches from the ribosome.

The conversion of the information from a sequence of codons in an RNA molecule into the sequence of amino acids in a newly synthesized polypeptide is called *translation*. A messenger RNA molecule is typically reused to make many copies of the same protein. Synthesis of a protein is usually terminated by destroying the messenger RNA. (The information [**11] for making more of that protein remains stored in DNA in the chromosomes.)

The translation of messenger RNA begins at a specific sequence of nucleotides that bind the RNA to the ribosome and specify which is the first codon that is to be translated. Translation then proceeds by reading nucleotides, three at a time, until a stop codon is reached. If some error were to occur that shifts the frame in which the nucleotides are read by one or two nucleotides, all of

the codons after this shift would be misread. For example, the sequence of codons [. . . *C-U-C-A-G-C-G-U-U-A-C-C-A*. . .] codes for the chain of amino acids [. .. leucine-serine-valine-threonine-. . .]. If the reading of these groups of three nucleotides is displaced by one nucleotide, such as [. . . *C-U-C-A-G-C-G-U-U-A-C-C-A* . . .], the resulting peptide chain would consist of [*898] [. . . serine-alanine-leucine-proline. . .]. This would be an entirely different peptide, and most probably an undesirable and useless one. Synthesis of a particular protein requires that the correct register or *reading frame* be maintained as the codons in the RNA are translated.

The function of messenger RNA is to carry [**12] genetic information (transcribed from DNA) to the protein synthetic machinery of a cell where its information is translated into the amino acid sequence of a protein. However, some kinds of RNA have other roles. For example, ribosomes contain several large strands of RNA that serve a structural function (*ribosomal RNA*). Chromosomes contain regions of DNA that code for the nucleotide sequences of structural RNAs and these sequences are transcribed to manufacture those RNAs. The DNA sequences coding for structural RNAs are still called genes even though the nucleotide sequence of the structural RNA is never translated into protein.

Man, other animals, plants, protozoa, and yeast are *eucaryotic* (or eukaryotic) organisms: their DNA is packaged in chromosomes in a special compartment of the cell, the nucleus. Bacteria (*procaryotic* or prokaryotic organisms) have a different organization. Their DNA, usually a circular loop, is not contained in any specialized compartment. Despite the incredible differences between them, all organisms, whether eucaryote or procaryote, whether man or mouse or lowly bacterium, use the same molecular rules to make proteins under the control of genes. [**13] In all organisms, codons in DNA are transcribed into codons in RNA which is translated on ribosomes into polypeptides according to the same genetic code. Thus, if a gene from a man is transferred into a bacterium, the bacterium can manufacture the human protein. Since most commercially valuable proteins come from man or other eucaryotes while bacteria are essentially little biochemical factories that can be grown in huge quantities, one strategy for manufacturing a desired protein (for example, insulin) is to transfer the gene coding for the protein from the eucaryotic cell where the gene normally occurs into a bacterium.

Bacteria containing genes from a foreign source (*heterologous* genes) integrated into their own genetic makeup are said to be *transformed*. When transformed bacteria grow and divide, the inserted heterologous genes, like all the other genes that are normally present in the bacterium (*indigenous* genes), are replicated and passed on to succeeding generations. One can produce large quantities of transformed bacteria that contain transplanted heterologous genes. The process of making large quantities of identical copies of a gene (or other fragment of DNA) [**14] by introducing it into procaryotic cells and then growing those cells is called *cloning* the gene. After growing sufficient quantities of the transformed bacteria, the biotechnologist must induce the transformed bacteria to *express* the cloned gene and make useful quantities of the protein. This is the purpose of the claimed invention.

In order to make a selected protein by expressing its cloned gene in bacteria, several technical hurdles must be overcome. First the gene coding for the specific protein must be isolated for cloning. This is a formidable task, but recombinant DNA technology has armed the genetic engineer with a variety of techniques to accomplish it. n7 Next the isolated gene must be introduced into the host bacterium. This can be done by incorporating the gene into a cloning vector. A *cloning vector* is a piece of DNA that can be introduced into bacteria and will then replicate itself as the bacterial cells grow and divide. Bacteriophage (viruses that infect bacteria) can be used as cloning vectors, but plasmids were the type used by appellants. A *plasmid* is a small circular loop of DNA found in bacteria, separate from the chromosome, that replicates [**15] like a chromosome. It is like a tiny auxilliary chromosome containing only a few genes. Because of their small size, plasmids are convenient for the molecular biologist to isolate and work with. Recombinant DNA technology can be used to modify plasmids by splicing in cloned eucaryotic [*899] genes and other useful segments of DNA containing control sequences. Short pieces of DNA can even be designed to have desired nucleotide sequences, synthesized chemically, and spliced into the plasmid. One use of such chemically synthesized linkers is to insure that the inserted gene has the same reading frame as the rest of the plasmid; this is a teaching of the Bahl reference cited against appellants. A plasmid constructed by the molecular geneticist can be inserted into bacteria, where it replicates as the bacteria grow.

n7 *See The Cell* at 185-194; *The Gene* at 208-10.

Even after a cloned heterologous gene has been successfully inserted into bacteria using a plasmid as a cloning vector, and replicates as [**16] the bacteria grow, there is no guarantee that the gene will be expressed, i.e., transcribed and translated into protein. A bacterium such as *E. coli* (the species of bacterium used

by appellants) has genes for several thousand proteins. At any given moment many of those genes are not expressed at all. The genetic engineer needs a method to "turn on" the cloned gene and force it to be expressed. This is the problem appellants worked to solve.

II. *Prior art*

Appellants sought to control the expression of cloned heterologous genes inserted into bacteria. They reported the results of their early efforts in a publication, the three authors of which included two of the three coinventor-appellants (the Polisky reference n8), that is undisputed prior art against them. Their strategy was to link the foreign gene to a highly regulated indigenous gene. Turning on expression of the indigenous gene by normal control mechanisms of the host would cause expression of the linked heterologous gene.

n8 Polisky, Bishop & Gelfand, *A plasmid cloning vehicle allowing regulated expression of eukaryotic DNA in bacteria*, 73 Proc. Nat'l Acad. Sci. USA 3900 (1976).

[**17]

As a controllable indigenous gene, the researchers chose a gene in the bacterium *E. coli* that makes beta-galactosidase. *Beta-galactosidase* is an enzyme needed to digest the sugar, lactose (milk sugar). When *E. coli* grows in a medium that contains no lactose, it does not make beta-galactosidase. If lactose is added to the medium, the gene coding for beta-galactosidase is expressed. The bacterial cell makes beta-galactosidase and is then able to use lactose as a food source. When lactose is no longer available, the cell again stops expressing the gene for beta-galactosidase.

The molecular mechanisms through which the presence of lactose turns on expression of the beta-galactosidase gene has been studied in detail, and is one of the best understood examples of how gene expression is regulated on the molecular level. The beta-galactosidase gene is controlled by segments of DNA adjacent to the gene. These *regulatory DNA sequences* (the general term used in Claim 1) include the *operator* and *promoter* sequences (specified in Claim 2). n9 The researchers constructed a plasmid containing the beta-galactosidase gene with its operator and promoter. This gene (with its [**18] regulatory sequences) was removed from the chromosome of *E. coli* where it is normally found and was transplanted to a plasmid that could be conveniently manipulated.

n9 The *promoter* is a sequence of nucleotides where the enzyme that synthesizes RNA, *RNA polymerase*, attaches to the DNA to start the transcription of the beta-galactosidase gene. The *operator* is an overlapping DNA sequence that binds a small protein present in the cell, the lactose repressor protein. The lactose repressor protein binds to the operator and physically blocks the RNA polymerase from properly attaching to the promoter so that transcription cannot proceed. Lactose molecules interact with the lactose repressor protein and cause it to change its shape; after this change in shape it moves out of the way and no longer prevents the RNA polymerase from binding to the promoter. Messenger RNA coding for beta-galactosidase can then be transcribed. *See generally The Cell* at 438-39; *The Gene* at 474-80.

Restriction endonucleases [**19] are useful tools in genetic engineering. These enzymes cut strands of DNA, but only at places where a specific sequence of nucleotides is present. For example, one restriction endonuclease, called *EcoRI*, cuts DNA only at sites where the nucleotide sequence is [. . .-G-A-A-T-T-C-. . .]. With restriction [*900] enzymes the genetic engineer can cut a strand of DNA at very specific sites into just a few pieces. With the help of "repair" enzymes, other pieces of DNA can be spliced onto the cut ends. The investigators found that the plasmid which they had constructed contained only two sequences that were cut by EcoRI. They were able to eliminate one of these sites that was unwanted. They were then left with a plasmid containing the beta-galactosidase gene with its regulatory sequences, and a single EcoRI site that was within the beta-galactosidase gene and close to its stop codon. They named this plasmid that they had constructed pBGP120.

The next step was to cut the plasmid open at its EcoRI site and insert a heterologous gene from another organism. The particular heterologous gene they chose to splice in was a segment of DNA from a frog that coded for ribosomal RNA. The frog [**20] gene was chosen as a test gene for reasons of convenience and availability. The new plasmid created by inserting the frog gene was similar to pBGP120, but its beta-galactosidase gene was incomplete. Some codons including the stop codon were missing from its end, which instead continued on with the sequence of the frog ribosomal RNA gene. The investigators named this new plasmid pBGP123. They inserted this plasmid back into *E. coli* and grew sufficient quantities for study. They then fed the *E. coli* with lactose. As they had intended, the lactose turned on transcription of the beta-galactosidase gene in the plasmid. RNA polymerase moved along the plasmid

producing a strange new kind of RNA: Each long strand of RNA first contained codons for the messenger RNA for beta-galactosidase and then continued without interruption with the codons for the frog ribosomal RNA. Thus, there was *readthrough* transcription in which the RNA polymerase first transcribed the indigenous (beta-galactosidase) gene and then "read through," i.e., continued into and through the adjacent heterologous (frog ribosomal RNA) gene. Although the RNA produced was a hybrid, it nevertheless contained a nucleotide [**21] sequence dictated by DNA from a frog. The researchers had achieved the first controlled transcription of an animal gene inside a bacterium.

The researchers had used a gene coding for a ribosomal RNA as their heterologous test gene. Ribosomal RNA is not normally translated into protein. Nevertheless, they were obviously interested in using their approach to make heterologous proteins in bacteria. They therefore examined the beta-galactosidase made by their transformed bacteria. Patrick O'Farrell, who was not a coauthor of the Polisky paper but was to become a coinventor in the patent application, joined as a collaborator. They found that beta-galactosidase from the transformed bacteria had a higher molecular weight than was normal. They concluded that the bacteria must have used their strange new hybrid RNA like any other messenger RNA and translated it into protein. When the machinery of protein synthesis reached the premature end of the sequence coding for beta-galactosidase it continued right on, three nucleotides at a time, adding whatever amino acid was coded for by those nucleotides, until a triplet was reached with the sequence of a stop codon. The resulting polypeptide chains [**22] had more amino acids than normal beta-galactosidase, and thus a higher molecular weight. The researchers published their preliminary results in the Polisky article. They wrote:

> If the normal translational stop signals for [beta]-galactosidase are missing in pBGP120, in-phase translational readthrough into adjacent inserted sequences might occur, resulting in a significant increase in the size of the [beta]-galactosidase polypeptide subunit. In fact, we have recently observed that induced cultures of pBGP123 contain elevated levels of [beta]-galactosidase of higher subunit molecular weight than wild-type enzyme (P. O'Farrell, unpublished experiments). We believe this increase results from translation of *Xenopus* [frog] RNA sequences covalently linked to [messenger] RNA for [beta]-galactosidase, resulting in a fused polypeptide.

Polisky at 3904.

Since ribosomal RNA is never translated in normal cells, the polypeptide chain produced [*901] by translating that chain was not a naturally occuring, identified protein. The authors of the Polisky paper explicitly pointed out that if one were to insert a heterologous gene coding for a protein into their [**23] plasmid, it should produce a "fused protein" consisting of a polypeptide made of beta-galactosidase plus the protein coded for by the inserted gene, joined by a peptide bond into a single continuous polypeptide chain:

> It would be interesting to examine the expression of a normally translated eukaryotic sequence in pBGP120. If an inserted sequence contains a ribosome binding site that can be utilized in bacteria, production of high levels of a readthrough transcript might allow for extensive translation of a functional eukaryotic polypeptide. In the absence of an independent ribosome binding site, the eukaryotic sequence would be translated to yield a peptide covalently linked to [beta]-galactosidase. The extent of readthrough translation under *lac* control will depend on the number of translatable codons between the EcoRI site and the first in-phase nonsense [i.e., stop] codon in the inserted sequence.

Id.

III. *The Claimed Invention*

Referring back to Claims 1 through 3, it can be seen that virtually everything in the claims was present in the prior art Polisky article. The main difference is that in Polisky the heterologous gene was a gene [**24] for ribosomal RNA while the claimed invention substitutes a gene coding for a predetermined protein. Ribosomal RNA gene is not normally translated into protein, so expression of the heterologous gene was studied mainly in terms of transcription into RNA. Nevertheless, Polisky mentioned preliminary evidence that the transcript of the ribosomal RNA gene was translated into protein. Polisky further predicted that if a gene that codes for a protein were to be substituted for the ribosomal RNA gene, "a readthrough transcript might allow for extensive translation of a functional eukaryotic polypeptide." Thus,

the prior art explicitly suggested the substitution that is the difference between the claimed invention and the prior art, and presented preliminary evidence suggesting that the method could be used to make proteins.

Appellants reduced their invention to practice some time in 1976 and reported their results in a paper that was published in 1978. n10 During 1977 they communicated their results to another group of researchers who used the readthrough translation approach to achieve the first synthesis of a human protein in bacteria. n11 Appellants filed an application to patent their [**25] invention on August 9, 1978, of which the application on appeal is a division.

n10 O'Farrell, Polisky & Gelfand, *Regulated expression by readthrough translation from a plasmid-encoded beta-galactosidase*, 134 J. Bacteriol. 645 (1978). The heterologous genes expressed in these studies were not predetermined, but were instead unidentified genes of unknown origin. The authors speculated that they were probably genes from *E. coli* that were contaminants in the source of beta-galactosidase genes. *Id.* at 648.

n11 Itakura, Hirose, Crea, Riggs, Heynecker, Bolivar & Boyer, *Expression in Escherichia coli of a chemically synthesized gene for the hormone somatostatin*, 198 Science 1056 (1977). A pioneering accomplishment of the Itakura group is that the gene was not from a human source, but instead was entirely synthesized in the laboratory using chemical methods. It is not clear whether the appellants communicated only the results reported in the Polisky publication or whether they communicated the complete claimed invention.

[**26]

IV. *The Obviousness Rejection*

The application was rejected under [HN1] *35 U.S.C. § 103.* The position of the examiner and the Board is, simply, that so much of the appellant's method was revealed in the Polisky reference that making a protein by substituting its gene for the ribosomal RNA gene in Polisky (as suggested by Polisky) would have been obvious to one of ordinary skill in the art at the time that the invention was made.

The claims specify that the heterologous gene should be inserted into the plasmid in the same orientation and with the same reading frame as the preceding portion of [*902] the indigenous gene. In view of this limitation, the § 103 rejection was based either on Polisky alone (supplemented by the fact that the importance of orientation and reading frame was well known in the prior art) or in combination with the Bahl reference which describes a general method for inserting a piece of chemically synthesized DNA into a plasmid. Bahl teaches that this technique could be used to shift the sequence of DNA inserted into a plasmid into the proper [**27] reading frame.

Appellants argue that at the time the Polisky article was published, there was significant unpredictability in the field of molecular biology so that the Polisky article would not have rendered the claimed method obvious to one of ordinary skill in the art. Even though there was speculation in the article that genes coding for proteins could be substituted for the ribosomal RNA gene and would be expressed as readthrough translation into the protein, this had never been done. Appellants say that it was not yet certain whether a heterologous protein could actually be produced in bacteria, and if it could, whether additional mechanisms or methods would be required. They contend that without such certainty the predictions in the Polisky paper, which hindsight now shows to have been correct, were merely invitations to those skilled in the art to try to make the claimed invention. They argue that the rejection amounts to the application of a standard of "obvious to try" to the field of molecular biology, a standard which this court and its predecessors have repeatedly rejected as improper grounds for a § 103 rejection. *E.g., In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988);* [**28] *In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 379 (Fed. Cir. 1986); In re Antonie, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977).*

[HN2] Obviousness under § 103 is a question of law. *Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597* (Fed. Cir.), *cert. denied, 481 U.S. 1052, 107 S. Ct. 2187, 95 L. Ed. 2d 843 (1987).* [HN3] An analysis of obviousness must be based on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any. *Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966). See, e.g., Custom Accessories, Inc. v. Jeffrey-Allan Indus., 807 F.2d 955, 958, 1 USPQ2d 1196, 1197 (Fed. Cir. 1986).* [**29] The scope and content of the prior art and the differences between the prior art and the claimed invention have been examined in sections II and III, *supra*. Appellants say that in 1976 those of ordinary skill in the arts of molecular biology and recombinant DNA

technology were research scientists who had "extraordinary skill in relevant arts" and "were among the brightest biologists in the world." Objective evidence of nonobviousness was not argued.

[HN4] With the statutory factors as expounded by *Graham* in mind and considering all of the evidence, this court must determine the correctness of the board's legal determination that the claimed invention as a whole would have been obvious to a person having ordinary skill in the art at the time the invention was made. We agree with the board that appellant's claimed invention would have been obvious in light of the Polisky reference alone or in combination with Bahl within the meaning of § 103. Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed [**30] invention, and evidence suggesting that it would be successful.

Appellants argue that after the publication of Polisky, successful synthesis of protein was still uncertain. They belittle the predictive value of the observation that expression of the transcribed RNA in Polisky produced beta-galactosidase with a greater than normal molecular weight, arguing that since ribosomal RNA is not normally translated, the polypeptide chains that were added to the end of the beta-galactosidase [*903] were "junk" or "nonsense" proteins. This characterization ignores the clear implications of the reported observations. The Polisky study directly proved that a readthrough transcript messenger RNA had been produced. The preliminary observation showed that this messenger RNA was read and used for successful translation. It was well known in the art that ribosomal RNA was made of the same nucleotides as messenger RNA, that any sequence of nucleotides could be read in groups of three as codons, and that reading these codons should specify a polypeptide chain that would elongate until a stop codon was encountered. The preliminary observations thus showed that codons beyond the end of the beta-galactosidase [**31] gene were being translated into peptide chains. This would reasonably suggest to one skilled in the art that if the codons inserted beyond the end of the beta-galactosidase gene coded for a "predetermined protein," that protein would be produced. In other words, it would have been obvious and reasonable to conclude from the observation reported in Polisky that since nonsense RNA produced nonsense polypeptides, if meaningful RNA was inserted instead of ribosomal RNA, useful protein would be the result. The relative shortness of the added chains is also not a source of uncertainty, since one skilled in the art would have known that a random sequence of nucleotides would produce a stop codon before the chain got too long. n12

n12 The patent application indicates that chains as long as 60 amino acids were added, which is hardly a trivial length of polypeptide.

Appellants complain that since predetermined proteins had not yet been produced in transformed bacteria, there was uncertainty as to whether this could [**32] be done, and that the rejection is thus founded on an impermissible "obvious to try" standard. It is true that this court and its predecessors have repeatedly emphasized that "obvious to try" is not the standard under § 103. However, the meaning of this maxim is sometimes lost. Any invention that would in fact have been obvious under § 103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless nonobvious?

The admonition that "obvious to try" is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. *E.g., In re Geiger, 815 F.2d at 688, 2 USPQ2d at 1278; Novo Industri A/S v. Travenol Laboratories, Inc., 677 F.2d 1202, 1208, 215 USPQ 412, 417 (7th Cir. 1982); In re Yates, 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981);* [**33] *In re Antonie, 559 F.2d at 621, 195 USPQ at 8-9.* In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1986), cert. denied, 480 U.S. 947, 107 S. Ct. 1606, 94 L. Ed. 2d 792 (1987); In re Tomlinson, 53 C.C.P.A. 1421, 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966).* Neither of these situations applies here.

[HN5] Obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for [**34] showing that the invention, although apparently obvious, was in law nonobvious. *In re Merck & Co., 800 F.2d at 1098, 231 USPQ at 380; Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1461,* [*904] *221 USPQ 481, 488*

(Fed. Cir. 1984); In re Papesch, 50 C.C.P.A. 1084, 315 F.2d 381, 386-87, 137 USPQ 43, 47-48 (CCPA 1963). For obviousness under § 103, all that is required is a reasonable expectation of success. *In re Longi, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985); In re Clinton, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976).* The information in the Polisky reference, when combined with the Bahl reference provided such a reasonable expectation of success.

Appellants published their pioneering studies of the expression of frog ribosomal RNA genes in bacteria more than a year before they applied for a patent. After providing virtually all of their method to the public without applying for a patent within a year, they foreclosed themselves from obtaining a patent on a method that would have been obvious from their publication to those of ordinary [**35] skill in the art, with or without the disclosures of other prior art. The decision of the board is

AFFIRMED.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANT:	JIA	EXAMINER:	MELLER, M. V.
SERIAL NO.:	10/091,362	ART UNIT:	1654
FILED:	MARCH 1, 2002	CONF. NO.	7281
TITLE:	IDENTIFICATION OF FREE-B-RING FLAVONOIDS AS POTENT COX-2 INHIBITORS		

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

BRIEF FOR APPELLANT

In furtherance of the Notice of Appeal to the Board of Appeals filed in the above-referenced application on October 29, 2003, Appellants Qi Jia, Timothy C. Nichols, Eric Rhoden and Scott Waite submit this brief in triplicate.

I. REAL PARTY IN INTEREST

The party in interest is UniGen Pharmaceuticals, Inc.

II. RELATED APPEALS AND INTERFERENCES

The undersigned legal representative of Appellant, hereby confirms that there are no known appeals or interferences relating to the present application, or any parent application, which will directly affect or be directly affected by the or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1, 4, 7, 22, 24-27 and 32-34 are pending in the application and stand rejected under a final Office Action mailed August 18, 2003. Claims 2, 3, 5, 6, 8-21, 23 and 28-31 have been canceled. The pending claims are set forth in the Appendix attached hereto. The rejection of all of the pending claims is hereby appealed.

IV. STATUS OF AMENDMENTS

The Amendments filed in this application have all been entered, and the claims in the attached Appendix accurately reflect the current status of the claims.

V. SUMMARY OF THE INVENTION

The present invention relates generally to a method for the prevention and treatment of COX-2 mediated diseases and conditions. The present invention implements a strategy that combines a series of biomolecular screens with a chemical dereplication process to identify active plant extracts and the particular compounds within those extracts that specifically inhibit COX-2 enzymatic activity and inflammation. A total of 1230 plant extracts were screened for their ability to inhibit the peroxidase activity associated with recombinant COX-2. This primary screen identified 22 plant extracts that were further studied for their ability to specifically and selectively inhibit COX-2 *in vitro* in both cell based and whole blood assays. Those extracts that were efficacious *in vitro* were then tested for their ability to inhibit inflammation *in vivo* using a both air pouch and topical ear-swelling models of inflammation when administered by multiple routes (IP and oral). These studies resulted in the discovery of botanical extracts that inhibited COX-2 activity and were efficacious both *in vitro* and *in vivo*. These studies also resulted in the identification of specific free-B-ring flavonoids associated with COX-2 inhibition in each of these extracts. (Specification, page 10, line 24 - page 11, line 7).

As provided in the Specification, (page 4, lines 7-11), the COX-2 enzyme catalyzes two separate reactions: the metabolism of arachidonic acid to form the unstable prostaglandin G2 (PGG2), a cyclooxygenase reaction and the conversion of PGG2 to the endoperoxide PGH2, a peroxidase reaction. The short-lived PGH2 non-enzymatically degrades to PGE2. Prostaglandins, including PGE2, contribute to the pain and fever associated with inflammation.

Inflammation is a complicated biological process involving DNA, mRNA gene expression, different cells, proteins, mediators, enzymes, chemical components, and normal

function of the microcardiovascular system and general immune functions. Using an inflammation animal model, croton oil induced mouse ear swelling, as an example, any agent that possesses any of the following mechanism of actions would yield anti-inflammatory output:

1. Croton oil absorption blocker;
2. Endothelial cells, leukocytes deactivator;
3. Cytokine production down regulator;
4. Histamine blocker;
5. Chemokines blocker;
6. Phospholipids A2 (PLA2) enzyme inhibitor;
7. PLA2 gene expression down regulator;
8. iNOS gene expression down regulator;
9. iNOS inhibitor;
10. Adhesion molecule expression inhibitor;
11. Adhesion molecule ligands;
12. Adhesion molecule receptor binder;
13. Lipoxygenase inhibitor;
14. Lipoxygenase gene down regulator;
15. Peroxidase inhibitor;
16. Free radical scavenging agent;
17. Prostaglandin E2 scavenging agent;
18. Cyclooxygenase gene down regulator; and
19. Cyclooxygenase inhibitor.

Essentially, any drugs, chemicals or natural products that interfere with any of the steps of the inflammation cascade may lead to the reduction in inflammation and can therefore be characterized as anti-inflammatory agents. Cyclooxygenase enzyme inhibitors block only the metabolism of arachidonic acid, which in turn leads to a decrease in the production of the pain-associated mediators prostaglandins. The result of the administration of a COX inhibitor will be a lessening of the pain and vasodilation, as well as, other symptoms related to inflammation.

Claim 1 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. Support for claim 1 can be found in Tables 7 and 8 of the Specification (pages 31 and 32). Claims 4 and 7, which depend from claim 1 are directed to the method of claim 1, wherein said free-B ring flavonoids are isolated from plant parts in general and specific plant parts (page 14, lines 6-8). Claim 22 is directed to the method of claim 1, wherein the composition is administered in a daily dosage of between 2.0 to 200 mg/kg of body weight (Example 9, pages 28-30 and Figures 3 and 4). Claim 32 is drawn to the method of claim 1, wherein the mixture of free-B-ring flavonoids contains at least 50% baicalein and baicalein. Claim 33 is drawn to the method of claim 1 wherein the composition is comprised of 10% to 25% of the mixture of free-B-ring flavonoids.

Support for claims 33 can be found in Example 10 and Table 8 on pages 30-32 of the Specification.

Claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid, wherein said free-B-ring flavonoid is selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. Support for claim 24 can be found in Table 4 on page 25 of the Specification. Claims 25 and 26, which depend from claim 24 are directed to the method of claim 24, wherein said free-B ring flavonoids are isolated from plant parts in general and specific plant parts (page 14, lines 6-8). Claim 27 is directed to the method of claim 24 wherein the composition is administered in a daily dosage of between 2.0 to 200 mg/kg of body weight (Example 9, pages 28-30 and Figures 3 and 4). Claim 34 is drawn to the method of claim 24, wherein the composition is comprised of 10% to 25% of the free-B-ring flavonoid. Support for claim 34 can be found in Example 10 and Table 8 on pages 30-32 of the Specification.

VI. ISSUES

1. Is the rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(a) as being anticipated by Nakajima *et al.* (2001) Planta Med 67:132-135; Krakauer *et al.* (2001) FEBS Letters 500:52-55; Kimura *et al.* (2001) Planta Med 67:331-334; Chi *et al.* (2001) Biochemical Pharmacology 61:1417-1427 or Chen *et al.* (2001) Biochemical Pharmacology 61:1195-1203 proper?

2. Is the rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(b) as being anticipated by Li *et al.* (2000) Immunopharmacology 49:295-306 or Meybeck, U.S. Pat. No. 5,643,598 proper?

3. Is the rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(e) as being anticipated by Xinxian, U.S. Pat. No. 6,290,995; Newmark *et al.*, U.S. Pat. No. 6,264,995; Newmark *et al.*, U.S. Pat. No. 6,391,346; Newmark *et al.*, U.S. Pat. No. 6,387,416 or Kuhrts, U.S. Pat. No. 6,475,530 proper?

4. Is the rejection of claims 1, 4, 7, 22, 24-27 and 32-34 under 35 U.S.C. § 103(a) over Nakajima *et al.* (2001) Planta Med 67:132-135; Krakauer *et al.* (2001) FEBS Letters

500:52-55; Kimura *et al.* (2001) Planta Med 67:331-334; Chi *et al.* (2001) Biochemical Pharmacology 61:1417-1427; Chen *et al.* (2001) Biochemical Pharmacology 61: 1417-1427; Xinxian, U.S. Pat. No. 6,290,995; Newmark *et al.*, U.S. Pat. No. 6,264,995; Newmark *et al.*, U.S. Pat. No. 6,391,346; Newmark *et al.*, U.S. Pat. No. 6,387,416; Kuhrts, U.S. Pat. No. 6,475,530; Li *et al.* (2000) Immunopharmacology 49:295-306 or Meybeck, U.S. Pat. No. 5,643,598 proper?

VII. GROUPING OF THE CLAIMS

For purposes of this appeal, the following groups of claims are considered separately patentable and do not stand or fall together: claims 1, 4, 7, 22, 32 and 33 (Group I), which are drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of a mixture of free-B-ring flavonoids and claims 24, 25, 26, 27 and 34 (Group II), which are drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of a single free-B-ring flavonoid, wherein said free-B-ring flavonoid is selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. In accordance with MPEP § 1206(c)(7), the reasons in support of separate patentability of these two groups of claims are that the claims of Group I are to the genus and the claims of Group II are to individual species within the genus. As discussed in detail below, some of the cited references disclose mixtures of flavonoids and some of the cited references disclose specific flavonoids. In light of this Appellant maintains that these two groups of claims are patentably distinct.

VIII. ARGUMENTS

A. Statement of the Relevant law Pertaining to 35 U.S.C. § 102 Rejections.

The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984); Alco Standard Corp. v. Tennessee Valley Auth., 1 USPQ2d 1337, 1341 (Fed. Cir. 1986). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic v. Genentech Inc., 18 USPQ2d 1001, 1010 (Fed. Cir. 1991, citations omitted). "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention either expressly or inherently." Atlas Powder Co. v. Ireco Inc., 190 F.3d. 1342, 1346 (Fed. Cir. (1999) (quoting In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997)).

1. The rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(a) is improper (Issue 1).

Claims 1, 4, 7 and 24-26 stand rejected under 35 U.S.C. § 102 (a) as being anticipated by Nakajima *et al.* (2001) Planta Med 67:132-135, Krakauer *et al.* (2001) FEBS Letters 500:52-55, Kimura *et al.* (2001) Planta Med 67:331-334, Chi *et al.* (2001) Biochemical Pharmacology 61:1417-1427 or Chen *et al.* (2001) Biochemical Pharmacology 61:1195-1203. The Examiner provides that each of these references "teach administering the claimed extract to a patient/host having a condition where the COX-2 enzyme needs to be inhibited." The Examiner reasons that although Applicant argues that the references do not teach that the COX-2 enzyme needs to be administered, each reference clearly describes that the extract, which inherently has the claimed compound in it, is being administered to treat a COX-2 condition, i.e. cancer, arthritis, asthma, etc.

The Nakajima *et al.* Reference

Nakajima *et al.* ((2001) Planta Med 67:132-135), teach the inhibition of the production of eotaxin by free-B-ring flavonoids isolated from *Scutellaria baicalensis* for the treatment of bronchial asthma. Specifically, four flavonoids isolated from *Scutellaria* root --baicalein, proxylin A, baicalin and skullcapflavon II-- were found to inhibit the production of eotaxin. Eotaxin is a protein produced by dermal fibroblasts in response to interleukin-4 and tumor necrosis factor-α and is related to bronchial diseases, such as allergies and asthma. This protein is not related to cyclooxygenase and has nothing to do with the metabolism of arachidonic acid. The inhibition of the production of eotaxin is completely unrelated to the inhibition of COX-2 activity.

Independent claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprising 10% to 100% of a mixture of free-B-ring flavonoids. The Nakajima *et al.* reference does not disclose or suggest that any of the four compounds or combinations thereof, function as COX-2 inhibitors. Furthermore, there is no evidence to suggest that there would be overlap between indications requiring an inhibitor of eotaxin and those requiring a COX-2 inhibitor. In fact, there is evidence in the literature that COX inhibitors can actually induce an asthma attack. Thus, the use of a COX-2 inhibitor would actually be contraindicated for treatment of asthmatic conditions. Additionally, as noted above, claim 1 is drawn to a composition comprising 10% to 100% of a mixture of free-B-ring

flavonoids. As stated above, the law is clear that to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention either expressly or inherently. When a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim. In the instant case, however, the Nakajima *et al.* reference provides no range for the amount of free-B-ring flavonoids in their composition. Thus, the Nakajima *et al.* reference does not expressly anticipate the claimed range. Furthermore, it cannot be concluded with any degree of certainty that the composition of the Nakajima *et al.* reference must fall within the claimed range. Thus, the Nakajima *et al.* reference does not inherently anticipate the claimed range. As such, Applicant maintains that the Nakajima *et al.* reference does not anticipate independent claim 1. Claims 4, 7 and 22, which depend from claim 1 are also not anticipated by this reference.

Independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a single free-B-ring flavonoid selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. For the reasons discussed above with respect to claim 1, Applicant maintains that the Nakajima *et al.* reference does not anticipate independent claim 24. Additionally, Applicant also maintains that the Nakijima *et al.* reference does not anticipate claims 25 and 26, which depend from claim 24.

The Krakauer *et al.* Reference

Krakauer *et al.* ((2001) FEBS Letters 500:52-55), disclose a method for the treatment of a number of diseases ranging from food poisoning and toxic shock to autoimmune diseases, by treatment with the free-B-ring flavonoid baicalin isolated from *Scutellaria baicalensis*. Krakauer *et al.* postulate that baicalin may be therapeutically useful for mitigating the pathogenic effects of staphylococcal exotoxins by inhibiting the signaling pathways activated by superantigens. There is no evidence that there is any relationship between the inhibition of the signaling pathways activated by superantigens and the inhibition of COX-2 activity.

As noted above, claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. The Krakauer *et al.* reference does not disclose or suggest treatment using a mixture of free-B-ring flavonoids. The Krakauer *et al.* reference also does not disclose or suggest that the free-B-ring flavonoid baicalin or any other free-B-ring flavonoid functions as

COX-2 inhibitor. Furthermore, although there may be some overlap between indications requiring the inhibition of the signaling pathways activated by superantigens and those requiring a COX-2 inhibitor, there is no evidence to suggest that the overlap would be substantial. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of the signaling pathways activated by superantigens would not be effective and visa versa. As stated above, the law is clear that to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention either expressly or inherently. Applicant maintains that the Krakauer *et al.* reference does not anticipate independent claim 1 or dependent claims 4, 7 and 22.

For the reasons discussed above with respect to independent claim 1, Applicant also maintains that the Krakauer *et al.* reference also does not anticipate independent claim 24. Additionally, independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid. As stated above, when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that fall within each of the ranges anticipates the claim. In the instant case, however, the Krakauer *et al.* reference provides no range for the amount of free-B-ring flavonoid in their composition. Thus, the Krakauer *et al.* reference does not expressly anticipate the claimed range. Furthermore, it cannot be concluded with any degree of certainty that the composition of the Krakauer *et al.* reference falls within the claimed range. Thus, the Krakauer *et al.* reference does not inherently anticipate the claimed range. As such, Applicant maintains that the Krakauer *et al.* reference does not anticipate independent claim 24 or dependent claims 25 or 26.

The Kimura *et al.* Reference

Kimura *et al.* ((2001) Planta Med 67:331-334), disclose the inhibition of adhesion molecule expression by the free-B-ring flavonoid baicalein. The baicalein was isolated from the roots of *Scutellaria baicalensis* and dissolved in ethanol to what appears to be a final concentration of less than 0.25% (Kimura *et al.*, page 332, col. 1, lines 1-3). Specifically, the free-B-ring flavonoid baicalein was found to inhibit the expression of both ELAM-1 and ICAM-1. Adhesion molecules are proteins, unrelated to both COX-2 activity and the arachidonic acid pathway. All other free-B-ring flavonoids tested including baicalin and wogonin were determined to have no effect on the inhibition of adhesion molecule expression.

Independent claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprising 10% to 100% of a mixture of free-B-ring flavonoids. The Kimura *et al.* reference does not disclose or suggest a composition of matter comprised of a mixture of free-B-ring flavonoids. In fact, this reference actually teaches away from compositions comprised of mixtures of flavonoids in that only one of the nine compounds tested was actually found to be active. The Kimura *et al.* reference also does not disclose or suggest that any of these compounds function as COX-2 inhibitors. Furthermore, although there may be some overlap between indications requiring inhibition of adhesion molecule expression and those requiring a COX-2 inhibitor, there is no evidence to suggest that the overlap would be one hundred percent. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of adhesion molecule expression would not be effective and visa versa. In fact, baicalin, one of the compounds determined to be inactive with respect to inhibition of adhesion molecule expression is an excellent inhibitor of COX-2 (see Specification, page 25, Table 4). In light of these comments, Applicant maintains that the Nakajima *et al.* reference does not anticipate independent claim 1 or dependent claims 4, 7 and 22.

Independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a single free-B-ring flavonoid. For the reasons discussed above with respect to claim 1, Applicant maintains that the Kimura *et al.* reference also does not anticipate independent claim 24. Additionally, independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid. As stated above, when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim. In the instant case, however, the Kimura *et al.* reference provides that the baicalein was dissolved in ethanol to a final concentration of less than 0.25% (Kimura *et al.*, page 332, col. 1, lines 1-3). This is not within the range of claim 24. Thus, the Kimura *et al.* reference neither expressly nor inherently anticipates the claimed range. As such, Applicant maintains that the Kimura *et al.* reference does not anticipate independent claim 24 or the claims that depend from this claim.

The Chi *et al.* Reference

Chi *et al.* ((2001) Biochemical Pharmacology 61:1195-1203) demonstrate that wogonin, a free-B-ring flavonoid, inhibits nitric oxide (NO) as well as PGE2 production via suppression of the induction/gene expression of both iNOS and COX-2 in LPS-induced RAWcells (page, 1200, col. 1). It was also found that wogonin inhibited PGE2 production more potently than NO production. Gene expression is a measure of mRNA production from DNA. Gene expression down regulation does not necessarily lead to inhibition of the protein itself. Direct COX-2 enzyme inhibition by wogonin was not measured in this study; however, the authors speculated that in addition to the inhibition of the gene expression of COX-2, wogonin also inhibited the activity of the enzyme itself. The authors provided that although the reason for the various sensitivities to inhibition by wogonin was not known, "[i]t may be explained in part by the fact that, in addition to the suppressive effects of wogonin on iNOS and COX-2 induction, it also inhibited COX-2 activity from the homogenate of LPS-induced RAW 264.7 cells" (page 1200; col. 1). It is clear that Chi *et al.* are merely speculating that wogonin directly inhibits the COX-2 enzyme. There was no direct measurement of COX-2 enzyme inhibition activity of wogonin in Chi's report and it was expressly stated that the reason for the various sensitivities was not known.

As noted above, claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. The Chi *et al.* reference does not disclose or suggest a composition of matter comprised of a mixture of free-B-ring flavonoids, but rather discloses the purported effect of one free-B-ring flavonoid, wogonin on COX-2 inhibition. With reference to the Specification, it can be seen that relative to the other free-B-ring flavonoids tested, such as baicalein (100% inhibition) and baicalin (97% inhibition), wogonin is actually a relatively poor COX-2 inhibitor (12% inhibition). (Specification, page 25, Table 4). As discussed in detail above, since claim 1 is drawn to a composition comprised of a mixture of free-B-ring flavonoids neither this claim nor the claims that depend from this claim are anticipated by the Chi *et al.* reference.

Independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a single free-B-ring flavonoid, wherein said free-B-ring flavonoid is selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. Claim 24 does not include the free-B-ring flavonoid wogonin and is therefore not anticipated by the Chi *et al.* reference. For

the same reason the claims that depend from independent claim 24 are also not anticipated by the Chi *et al.* reference.

The Chen *et al.* Reference

Chen *et al.* ((2001) Biochemical Pharmacology 61:1417-1427) examined three free-B-ring flavonoids: wogonin, baicalin and baicalein for their effects on LPS-induced NO production and iNOS and COX-2 gene expression. As noted above, gene expression is a measure of mRNA production from DNA and further, gene expression down regulation does not necessarily lead to inhibition of the protein itself. In this study, Chen *et al.* also indirectly examined the effects of baicalin, baicalein and wogonin on iNOS and COX-2 enzyme activity, using a cell model of LPS stimulated prostaglandin E2 (PGE2) production, as described in Section 3.3 beginning on page 1420 of the reference. The authors conclude that "[w]ogonin, but not baicalin or baicalein, inhibited LPS-induced COX-2 expression." (Page 1426, col. 1). The authors also expressly provide that "[t]hese compounds [wogonin, baicalin and baicalein] did not affect iNOS and COX-2 (enzyme) activity." (Page 1426, col. 1). Thus, Chen *et al.* found no direct enzyme inhibition by any of the three free-B-ring flavonoids evaluated.

As noted above, claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. The Chen *et al.* reference does not disclose or suggest a composition of matter comprised of a mixture of free-B-ring flavonoids. In fact, this reference clearly teaches away from the use of compositions comprised of mixtures of flavonoids for the inhibition of COX-2 in that Chen *et al.* actually reports that no direct enzyme inhibition by any of the free-B-ring flavonoids was found. As discussed in detail above, since claim 1 and its dependent claims are drawn to a composition comprised of a mixture of free-B-ring flavonoids these claims are not anticipated by the Chen *et al.* reference.

Independent claim 24 is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a single free-B-ring flavonoid, wherein said free-B-ring flavonoid is selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. As noted above, claim 24 does not include the free-B-ring flavonoid wogonin and the Chen *et al.* reference expressly provides that baicalein and baicalin do not inhibit the COX-2 enzyme. Claim 24 and its dependent claims are therefore not anticipated by the Chen *et al.* reference.

2. The rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(b) is improper (Issue 2).

Claims 1, 4, 7 and 24-26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Li *et al.* (2000) Immunopharmacology 49:295-306 or Meybeck U.S. Pat. No. 5,643,598. The Examiner provides that each of these references "teach administering the claimed extract to a patient/host having a condition where the COX-2 enzyme needs to be inhibited." The Examiner reasons that although Applicant argues that the references do not teach that the COX-2 enzyme needs to be administered, each reference clearly describes that the extract, which inherently has the claimed compound in it, is being administered to treat a COX-2 condition, i.e. cancer, arthritis, asthma, etc.

The Li *et al.* Reference

Li *et al.* ((2000) Immunopharmacology 49:295-306) teach the inhibition of the binding of a number of chemokines to human leukocytes via selective binding to chemokine ligands by the free-B-ring flavonoid baicalin, isolated from *Scutellaria baicalensis*. Chemokines are chemotactic molecules that attract immune cells, helping them to "home" to sites of inflammation. Frequently, the cells producing these regulatory molecules also bear receptors for them, participating in a complex network of self-regulating and local interactions that orchestrate the proliferation of immune cells and the subsequent decline of immune activity. COX mediated inflammation pathways are downstream biological responses. Inhibition of the binding of chemokines is unrelated to the arachidonic acid metabolism by COX-2.

As noted above, claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. The Li *et al.* reference does not disclose or suggest using a mixture of free-B-ring flavonoids. The Li *et al.* reference also does not disclose or suggest that the free-B-ring flavonoid baicalin or any other free-B-ring flavonoid functions as a COX-2 inhibitor. Furthermore, although there may be some overlap between indications requiring an inhibitor of the binding of chemokines to human leukocytes by the free-B-ring flavonoid baicalin and those requiring a COX-2 inhibitor, there is no evidence to suggest that the overlap would be substantial. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of the binding of chemokines to human leukocytes would not be effective and visa versa. As stated above, the law is clear that to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention

either expressly or inherently. Applicant maintains that the Li *et al.* reference does not satisfy this criterion and therefore does not anticipate independent claim 1 or the claims that depend from this claim.

For the reasons discussed above with respect to independent claim 1, Applicant maintains that the Li *et al.* reference also does not anticipate independent claim 24.

The Meybeck Reference

Meybeck (U.S. Pat. No. 5,643,598) teaches a method of formulating *Scutellaria* extracts or at least one active substance isolated from such extracts in liposomes for topical usage having anti-allergic, anti-inflammatory and anti-aging activity. A number of free-B-ring flavonoids, including wogonin, baicalein, scullcapflavone II and baicalin are characterized as antibacterial compounds, as described in the section entitled "Extraction and Isolation of the Antibacterial Components" (Specification, col. 6) and illustrated in Figure 2. With reference to Table II (Specification, col. 11-12), the *Scutellaria* extract in gel exhibited no anti-inflammatory effect (1.1%) when not incorporated into a liposome as illustrated in Figure 1, Table II (Specification, col. 11) and as provided in the Specification (col. 12, lines 8-11). Only the liposome formulated extract had a significant anti-inflammatory effect (69.6%). A moderate effect (30.7%) was observed from the empty liposome. Thus, the Meybeck reference actually teaches away from the method of this invention with respect to the anti-inflammatory activity of these compositions. Additionally, Meybeck neither teaches nor suggests the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors, therefore Meybeck does not anticipate the claims of this invention, which are drawn to the inhibition of the COX-2 enzyme. Finally, the amount of free-B-ring flavonoid or mixtures thereof in the formulation taught by Meybeck is significantly less than the amount set forth in the claims. Meybeck claims a *Scutellaria* extract (alcoholic, aqueous or hydroalcoholic) formulated in a ratio of between 0.00001 to 2% by weight of the extract or any active substance contained in the extract, in an anti-inflammatory composition for topical applications. (Col. 6, lines 45-50). The claims of this invention are drawn to a composition comprising 10% to 100% (claims 1 and 24) of the free-B-ring flavonoid or mixtures thereof.

As stated above, anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. For all of the reasons discussed above, Applicant maintains that the Meybeck reference does not satisfy this criterion and therefore does not anticipate independent claims 1 or 24 of the instant invention.

3. The rejection of claims 1, 4, 7 and 24-26 under 35 U.S.C. § 102(e) is improper (Issue 3).

Claims 1, 4, 7 and 24-26 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Xinxian, U.S. Pat. No. 6,290,995; Newmark *et al.*, U.S. Pat. No. 6,264,995; Newmark *et al.*, U.S. Pat. No. 6,391,346; Newmark *et al.*, U.S. Pat. No. 6,387,416 or Kuhrts, U.S. Pat. No. 6,475,530. The Examiner provides that each of these references "teach administering the claimed extract to a patient/host having a condition where the COX-2 enzyme needs to be inhibited." The Examiner provides that although Applicants argue that the extract is being used for a different purpose other than in a method for inhibiting COX-2, the fact of the matter is that each reference clearly describes that the extract is being administered to treat a COX-2 condition, i.e. cancer, arthritis, asthma, etc.

The Xinxian Reference

Xinxian (U.S. Pat. No. 6,290,995) teaches a method for producing a pharmaceutical composition of baicalin in combination with the alkaloid berberine for use in the treatment of cancer and control of cancer cells. Example 5 demonstrates that baicalin inhibits DNA synthesis of TPA-stimulated mouse epidermis and therefore prevents epidermis cancer (col. 6, lines 22-25). Example 6 demonstrates the effectiveness of baicalin in the treatment of gastric cancer. In this example, the mixture of baicalin and berberine is shown to inhibit levels of DNA methylation, p^{53} mutations, ^{17}p allelic loss of cancer cells and increase the function of tumor suppressor of gastric cancer cells. Example 7 demonstrates that baicalin inhibits oncogenes and Example 8 demonstrates that baicalin inhibits tumor cell proliferation and prevents tumor incidence in an animal model *in vivo*. The Xinxian patent does not teach or suggest that the free-B-ring flavonoid, baicalin, isolated from *Scutellaria baicalensis* inhibits COX-2 activity. Nor does the Xinxian patent disclose or suggest an active composition of matter comprised of a mixture of free-B-ring flavonoids. Finally, although there may be some overlap between indications requiring an inhibitor of DNA synthesis etc. and those requiring a COX-2 inhibitor, there is no evidence to suggest that the overlap would be substantial. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of DNA synthesis would not be effective and visa versa. As stated above, the law is clear that to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention either expressly or inherently. For all of the reasons discussed above with respect to

the other references cited by the Examiner, Applicant maintains that the Xinxian reference does not anticipate independent claims 1 or 24 of the instant invention.

The Newmark References

Newmark *et al.* (U.S. Pat. No. 6,264,995, the '995 patent), teach an herbal composition, which contains extracts from 13 different plants, including *Scutellaria baicalensis*. The patent provides that the extract reduces inflammation in bones and joints by inhibiting the COX-2 enzyme. The only definition of the *Scutellaria baicalensis* root extract is 5:1, which generally refers to 5 parts of plant root yielding one part of the extract. Considering that more than 58 compounds have been isolated from *Scutellaria baicalensis*, a hydroalcoholic extract could contain any number of compounds including, but not limited to alkaloids, benzyl alcohol glycosides, lignans, benzopyranones, amino acids, phytosterols, monosugars, flavones and flavanones. The '995 patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. The present invention, on the other hand, discloses and claims a specific class of compounds, free-B-ring flavonoids, as having COX-2 inhibitory activity. Thus, even though the Newmark *et al.* composition likely contains free-B-ring flavonoids, there is no disclosure or suggestion that these compounds are COX-2 inhibitors.

Applicant maintains that there are many advantages to isolating and identifying specific biologically active compounds from a composition of matter that could contain literally thousands of compounds. Once identified, a class of compounds can be purified and concentrated to provide a more effective biological agent. Additionally, the compounds can be chemically modified to provide a composition of matter that is more active and/or less toxic. Finally, once isolated and identified a specific compound or class of compounds can be studied to determine the exact biological activity and mode of action, thus enabling more specific targeting of the compound or class of compounds for the treatment of particular diseases or conditions.

Additionally, with reference to the Table provided in the Newmark patent (col. 12), the extract of *Scutellaria baicalensis* accounted for approximately 2.6% by weight of the formulation. As discussed in detail below, the amount of free-B-ring flavonoid or mixtures thereof in the formulation taught by Newmark *et al.* is significantly less than the amount set forth in the claims of the instant invention. In the case of chemical compounds slight changes, including a mere change in the amount of a compound, have been found to be sufficient to

change an old compound into a new one. (Schering Corp. v. Precision-Cosmet Co. 614 F. Supp. 1368, 1374 (D. Del. 1985)). The law is clear that new uses of known processes may be patentable. Therefore, Applicant maintains that Newmark *et al.* does not anticipate independent claims 1 and 24.

In the roots of *Scutellaria baicalensis*, the baicalin content (which accounts for approximately 80% of the total free-B-ring flavonoid content) is approximately 10% of the weight of the roots. If an average of 10% is used as a benchmark, one can obtain 10 grams of baicalin from 100 grams of dry root, assuming the extraction efficiency is 100%. With reference to the Table provided in the Newmark patent (col. 12), the *Scutellaria Baicalensis* root extract used in the formulation is a 5:1 extract, which means from 5 parts (grams/kilograms) of root, 1 part (grams/kilograms) of extract by weight is obtained. The Table further provides that the quantity of the extract used in the formulation is 20 mg. Thus, 100 mg of dry root was required to provide this amount of extract (20 mg x 5 = 100 mg dry root). Assuming for the sake of argument, that the maximum amount of baicalin/free-B-ring flavonoids was extracted, the baicalin content in the 20 mg of root extract would be approximately 10 mg. (100 mg root extract x 10% = 10 mg baicalin in the 20 mg of root extract). Thus, the maximum purity of baicalin in the 20 mg of extract is 50%. Thus, based on the information provided in the Table, the maximum % of baicalin in Newmark's formulation is 1.3% (10 mg/770 mg total dry weight). Finally, if 20 mg of a 5:1 extract (10 mg baicalin) is administered to an average weight adult at 75 kg (165 lb) body weight, the dosage range for the extract is 0.27 mg/kg (0.14 mg/kg for baicalin). The claims of this invention are drawn to administering a free-B-ring flavonoid or mixture thereof wherein the content of said flavonoid or mixture thereof is 10% to 100% (claims 1 and 24) and the dosage range is 2.0 to 200 mg/kg of body weight. Therefore, the Newmark *et al.* patent does not anticipate the claims.

Newmark *et al.* (U.S. Pat. No. 6,387,416), describe an orally or topically administered composition capable of reducing inflammation. With reference to the Table (Specification col. 8-9), the maximum % of baicalin in the formulation described in this patent is approximately the same as the '995 patent discussed above (20 mg of a 5:1 extract/760 mg total). Additionally, as discussed above Newmark *et al.* neither teach nor suggest the use of free-B-ring flavonoids as COX-2 inhibitors. Therefore, based on the reasoning above, this patent does not anticipate the claims of this invention, as amended.

Newmark *et al.* (U.S. Pat. No. 6,391,346), describe an orally administered composition capable of reducing inflammation in animals. The composition contains 13 extracts, including an extract from the plant *Scutellaria baicalensis*. The only definition of the *Scutellaria baicalensis* root extract provided in the Specification is that it is 5:1, which as noted above, generally refers to 5 parts of plant roots yielding one part of the extract. Also as noted above, considering that more than 58 compounds have been isolated from *Scutellaria baicalensis*, a hydroalcoholic extract could contain any number of compounds including, but not limited to alkaloids, benzyl alcohol glycosides, lignans, benzopyranones, amino acids, phytosterols, monosugars, flavones and flavanones. Additionally, the patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. The extract from *Scutellaria baicalensis* accounted for approximately 12% to 18% by weight of total weight of the formulation. This amounts to a maximum of 6% to 9% by weight of free-B-ring flavonoids in the formulation. As discussed above, the claims of the instant invention provide that the free-B-ring flavonoid or mixture thereof is present in an amount greater than 10%. Therefore, based on the above reasoning, this patent does not anticipate the claims of this invention.

The Kuhrts Reference

Kuhrts (U.S. Pat. No. 6,475,530) describe weight loss compositions that combine a weight loss effective compound and a botanical COX-2 inhibitor. The plant "*Scutellaria baicalensis*" was referred to in the patent as a COX-2 inhibitor. There is no further description, however, of the material or extract of *Scutellaria baicalensis* being used. Nor is there any reference to amounts or dosage. "*Scutellaria baicalensis*" is the Latin name of a specific species of plant. It is commonly known that different parts of a plant contain totally different types of compounds in different concentrations. To date, there have been more than 58 compounds isolated from various parts of *Scutellaria baicalensis*. These compounds include alkaloids, benzyl alcohol glycosides, lignans, benzopyranones, amino acids, phytosterols, monosugars, flavones, and flavanones. The Kuhrts patent provides no examples to substantiate the claim of a COX inhibitor from *Scutellaria baicalensis*. Nor does the Kuhrts patent teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. Therefore, for the reasons discussed above, Applicant maintains that the Kuhrts patent does not anticipate the claims of the instant invention.

B. Statement of the Relevant law Pertaining to 35 U.S.C. § 103 Rejections.

The Examiner bears the burden of establishing a prima facie case of obviousness. In determining obviousness, one must focus on Applicant's invention as a whole. Symbol Technologies Inc. v. Opticon Inc., 19 USPQ2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is:

> whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success. . . . Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure.

In re Dow Chemical, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

Where the prior art teaches generically, and no indication is given as to which of the parameters or choices is desirable or likely to be successful, then the fact that the claimed invention is within the generic teachings of the prior art does not render the claimed invention obvious. Under such circumstances, i.e., where the artisan is invited to simply try each of numerous possible choices, *prima facie* obviousness is not established. Instead, it is said that the invitation to investigate various possibilities of a genus can, at most, only render the claimed invention "obvious to try," which is not the proper standard under Section 103. In re O'Farrell, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988).

4. The rejection of claims 1, 4, 7, 22, 24-27 and 32-34 under 35 U.S.C. § 103(a) is improper (Issue 4).

Claims 1, 4, 7, 22, 24-27 and 32-34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nakajima *et al.* (2001) Planta Med 67:132-135; Krakauer *et al.* (2001) FEBS Letters 500:52-55; Kimura *et al.* (2001) Planta Med 67:331-334; Chi *et al.* (2001) Biochemical Pharmacology 61:1417-1427; Chen *et al.* (2001) Biochemical Pharmacology 61: 1417-1427; Xinxian, U.S. Pat. No. 6,290,995; Newmark *et al.*, U.S. Pat. No. 6,264,995; Newmark *et al.*, U.S. Pat. No. 6,391,346; Newmark *et al.*, U.S. Pat. No. 6,387,416; Kuhrts, U.S. Pat. No. 6,475,530; Li *et al.* (2000) Immunopharmacology 49:295-306 or Meybeck, U.S. Pat. No. 5,643,598. The Examiner provides that each of these references "teach administering the claimed extract to a patient/host having a condition where the COX-2 enzyme needs to be inhibited." The Examiner provides that although Applicants argue that the extract is being used for a different purpose other than in a method for inhibiting COX-2, the fact of the matter is that each reference clearly

describes that the extract is being administered to treat a COX-2 condition, i.e. cancer, arthritis, asthma, etc.

Appellant asserts that the cited references either alone or in combination, do not disclose or suggest the present invention, and therefore, do not render the present invention obvious. As noted above, the present invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprising 10% to 100% of a free-B-ring flavonoid (claim 24) or mixtures thereof (claim 1). The present invention implements a strategy that combines a series of biomolecular screens with a chemical dereplication process to identify active plant extracts and the particular compounds within those extracts that specifically inhibit COX-2 enzymatic activity and inflammation. A total of 1230 plant extracts were screened for their ability to inhibit the peroxidase activity associated with recombinant COX-2. This primary screen identified 22 plant extracts that were further studied for their ability to specifically and selectively inhibit COX-2 *in vitro* in both cell based and whole blood assays. Those extracts that were efficacious *in vitro* were then tested for their ability to inhibit inflammation *in vivo* using a both air pouch and topical ear-swelling models of inflammation when administered by multiple routes (IP and oral). These studies resulted in the discovery of botanical extracts that inhibited COX-2 activity and were efficacious both *in vitro* and *in vivo*. These studies also resulted in the identification of specific free-B-ring flavonoids associated with COX-2 inhibition in each of these extracts. (Specification, page 10, line 24- page 11, line 7). As discussed in detail below, Appellant asserts that the discovery of this class of COX-2 inhibitors was not motivated by the prior art relied upon by the Examiner and further that this class of COX-2 inhibitors is not rendered obvious by the art relied upon by the Examiner.

Nakajima *et al.* ((2001) Planta Med 67:132-135), teach the inhibition of the production of eotaxin by free-B-ring flavonoids isolated from *Scutellaria baicalensis* for the treatment of bronchial asthma. Specifically, four flavonoids isolated from *Scutellaria* root --baicalein, proxylin A, baicalin and skullcapflavon II-- were found to inhibit the production of eotaxin. As provided above, this protein is not related to cyclooxygenase and has nothing to do with the metabolism of arachidonic acid. The Nakajima *et al.* reference does not disclose or suggest that any of the four compounds or combinations thereof, function as COX-2 inhibitors. Furthermore, there is no evidence to suggest that there would be overlap between indications requiring an inhibitor of eotaxin and those requiring a COX-2 inhibitor. Applicant asserts therefore that one would not be motivated by this reference to use a free-B-ring flavonoid or mixtures thereof as a

COX-2 inhibitor. As stated above, both the suggestion and the expectation of success must be found in the cited reference.

Krakauer *et al.* ((2001) FEBS Letters 500:52-55), disclose a method for the treatment of a number of diseases ranging from food poisoning and toxic shock to autoimmune diseases by treatment with the free-B-ring flavonoid baicalin isolated from *Scutellaria baicalensis*. Krakauer *et al.* postulate that baicalin may be therapeutically useful for mitigating the pathogenic effects of staphylococcal exotoxins by inhibiting the signaling pathways activated by superantigens. There is no evidence that there is any relationship between the inhibition of the signaling pathways activated by superantigens and the inhibition of COX-2 activity. For the reasons stated above, Applicant asserts therefore that one would not be motivated by this reference to use a free-B-ring flavonoid or mixtures thereof as potential COX-2 inhibitors.

Kimura *et al.* ((2001) Planta Med 67:331-334), disclose the inhibition of adhesion molecule expression by the free-B-ring flavonoid baicalein. The baicalein was isolated from the roots of *Scutellaria baicalensis* and dissolved in ethanol to what appears to be a final concentration of less than 0.25% (Kimura *et al.*, page 332, col. 1, lines 1-3). Specifically, the free-B-ring flavonoid baicalein was found to inhibit the expression of both ELAM-1 and ICAM-1. All other free-B-ring flavonoids tested including baicalin and wogonin were determined to have no effect on the inhibition of adhesion molecule expression. Independent claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprising 10% to 100% of a mixture of free-B-ring flavonoids. The Kimura *et al.* reference does not disclose or suggest a composition of matter comprised of a mixture of free-B-ring flavonoids. In fact, as provided above, this reference actually teaches away from compositions comprised of mixtures of flavonoids in that only one of the nine compounds tested was actually found to be active. The Kimura *et al.* reference also does not disclose or suggest that any of these compounds function as COX-2 inhibitors. In fact, baicalin, one of the compounds determined to be inactive with respect to inhibition of adhesion molecule expression is an excellent inhibitor of COX-2 (see Specification, page 25, Table 4).

Additionally, the claims of the instant invention are drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid. The Kimura *et al.* reference provides that the baicalein was dissolved in ethanol to a final concentration of less than 0.25% (Kimura *et al.*, page 332, col. 1, lines 1-3). This is not within the range of any of the claims of this invention. The Examiner provides, however, that

the amounts used are simply the choice of the artisan to use in an effort to optimize the desired results. In response to this, however, if one does not even know that the compounds of interest are COX-2 inhibitors, one would not be motivated to optimize an unknown result by altering concentration. For the reasons discussed above, Applicant asserts therefore that one would not be motivated by this reference to use a free-B-ring flavonoid or mixtures thereof as potential COX-2 inhibitors.

Chi *et al.* ((2001) Biochemical Pharmacology 61:1195-1203) demonstrate that wogonin, a free-B-ring flavonoid, inhibits nitric oxide (NO) as well as PGE2 production via suppression of the induction/gene expression of both iNOS and COX-2 in LPS-induced RAWcells (page, 1200, col. 1). The authors provided that although the reason for the various sensitivities to inhibition by wogonin was not known, "[i]t may be explained in part by the fact that, in addition to the suppressive effects of wogonin on iNOS and COX-2 induction, it also inhibited COX-2 activity from the homogenate of LPS-induced RAW 264.7 cells" (page 1200; col. 1). As noted above, claim 1 of the instant invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a mixture of free-B-ring flavonoids. The Chi *et al.* reference does not disclose or suggest a composition of matter comprised of a mixture of free-B-ring flavonoids, but rather discloses the purported effect of one free-B-ring flavonoid, wogonin on COX-2 inhibition. With reference to the Specification, it can be seen that relative to the other free-B-ring flavonoids tested, such as baicalein (100% inhibition) and baicalin (97% inhibition), wogonin is actually a relatively poor COX-2 inhibitor (12% inhibition). (Specification, page 25, Table 4).

Independent claim 24 is drawn to drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid, wherein said free-B-ring flavonoid is selected from the group consisting of, baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin. As amended, claim 24 excludes the free-B-ring flavonoid wogonin.

Chen *et al.* ((2001) Biochemical Pharmacology 61:1417-1427) examined three free-B-ring flavonoids: wogonin, baicalin and baicalein for their effects on LPS-induced NO production and iNOS and COX-2 gene expression. In this study, Chen *et al.* also indirectly examined the effects of baicalin, baicalein and wogonin on iNOS and COX-2 enzyme activity, using a cell model of LPS stimulated prostaglandin E2 (PGE2) production. The authors conclude that "[w]ogonin, but not baicalin or baicalein, inhibited LPS-induced COX-2 expression." (Page

1426, col. 1). The authors also expressly provide that "[t]hese compounds [wogonin, baicalin and baicalein] did not affect iNOS and COX-2 (enzyme) activity." (Page 1426, col. 1). Thus, Chen *et al.* found no direct enzyme inhibition by any of the three free-B-ring flavonoids evaluated.

As noted above, the present invention is drawn to a method for inhibiting the COX-2 enzyme by administering a composition comprised of 10% to 100% of a free-B-ring flavonoid or mixtures thereof. The Chen *et al.* reference actually teaches away from the method of this invention in that Chen *et al.* report that no direct enzyme inhibition by any of the free-B-ring flavonoids was found. Furthermore, when combined with the Chi reference, Applicant maintains that there would be little motivation to use a free-B-ring flavonoid or mixtures thereof as potential COX-2 inhibitors. While the Chi *et al.* reference merely speculates that wogonin inhibits the COX-2 enzyme, the Chen *et al.* reference expressly provides that there was no direct COX-2 inhibition by any of the free-B-ring flavonoids tested.

Li *et al.* ((2000) Immunopharmacology 49:295-306) teach the inhibition of the binding of a number of chemokines to human leukocytes via selective binding to chemokine ligands by the free-B-ring flavonoid baicalin, isolated from *Scutellaria baicalensis*. As noted above, inhibition of the binding of chemokines is unrelated to the arachidonic acid metabolism by COX-2. The Li *et al.* reference does not disclose or suggest using a mixture of free-B-ring flavonoids. The Li *et al.* reference also does not disclose or suggest that the free-B-ring flavonoid baicalin or any other free-B-ring flavonoid functions as a COX-2 inhibitor. Furthermore, although there may be some overlap between indications requiring an inhibitor of the binding of chemokines to human leukocytes by the free-B-ring flavonoid baicalin and those requiring a COX-2 inhibitor, there is no evidence to suggest that the overlap would be substantial. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of the binding of chemokines to human leukocytes would not be effective and visa versa. For the reasons discussed above, Applicant asserts therefore that one would not be motivated by this reference to use a free-B-ring flavonoid or mixtures thereof as potential COX-2 inhibitors.

Meybeck (U.S. Pat. No. 5,643,598) teaches a method of formulating *Scutellaria* extracts or at least one active substance isolated from such extracts in liposomes for topical usage having anti-allergic, anti-inflammatory and anti-aging activity. A number of free-B-ring flavonoids, including wogonin, baicalein, scullcapflavone II and baicalin are characterized as antibacterial

compounds. With reference to Table II of the Maybeck reference (Specification, col. 11-12), the *Scutellaria* extract in gel exhibited **no** anti-inflammatory effect (1.1%) when not incorporated into a liposome as illustrated in Figure 1, Table II (Specification, col. 11) and as provided in the Specification (col. 12, lines 8-11). Thus, the Meybeck reference actually teaches away from the method of this invention with respect to the anti-inflammatory activity of these compositions. Additionally, Meybeck neither teaches nor suggests the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. Finally, the amount of free-B-ring flavonoid or mixtures thereof in the formulation taught by Meybeck is significantly less than the amount set forth in the claims of the instant invention. Meybeck claims a *Scutellaria* extract (alcoholic, aqueous or hydroalcoholic) formulated in a ratio of between 0.00001 to 2% by weight of the extract or any active substance contained in the extract, in an anti-inflammatory composition for topical applications. (Col. 6, lines 45-50). The claims of this invention are drawn to a composition comprising 10% to 100% (claims 1 and 24) or 10% to 25% (claims 33 and 34) of the free-B-ring flavonoid or mixtures thereof. As provided above, although the Examiner provides that the amounts used are simply the choice of the artisan in an effort to optimize the desired results, if one does not even know that the compounds of interest are COX-2 inhibitors, one would not be motivated to optimize an unknown result by altering concentrations.

Xinxian (U.S. Pat. No. 6,290,995) teaches a method for producing a pharmaceutical composition of baicalin for use in the treatment of cancer and control of cancer cells. Baicalin is shown to inhibit DNA synthesis, to inhibit levels of DNA methylation, p^{53} mutations, ^{17}p allelic loss of cancer cells and to inhibit oncogenes. The Xinxian patent does not teach or suggest that the free-B-ring flavonoid baicalin inhibits COX-2 activity. Nor does the Xinxian patent disclose or suggest an active composition of matter comprised of a mixture of free-B-ring flavonoids. Finally, although there may be some overlap between indications requiring an inhibitor of DNA synthesis etc. and those requiring a COX-2 inhibitor, there is no evidence to suggest that this overlap would be substantial. That is to say that there are likely to be diseases or conditions in which a COX-2 inhibitor would be indicated for which an inhibitor of DNA synthesis would not be effective and visa versa. For all of the reasons discussed above with respect to the other references cited by the Examiner, Applicant maintains that the Xinxian reference does not render the present invention obvious.

Newmark *et al.* (U.S. Pat. No. 6,264,995, the '995 patent), teach an herbal composition, which contains extracts from 13 different plants, including *Scutellaria baicalensis*. The patent

provides that the extract reduces inflammation in bones and joints by inhibiting the COX-2 enzyme. The only definition of the *Scutellaria baicalensis* root extract is 5:1, which generally refers to 5 parts of plant root yielding one part of the extract. Considering that more than 58 compounds have been isolated from *Scutellaria baicalensis*, a hydroalcoholic extract could contain any number of compounds. The '995 patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. The present invention, on the other hand, discloses and claims a specific class of compounds, free-B-ring flavonoids, as having COX-2 inhibitory activity. Thus, even though the Newmark *et al.* composition likely contains free-B-ring flavonoids, there is no disclosure or suggestion that these compounds are COX-2 inhibitors.

Applicant maintains that there are many advantages to isolating and identifying specific biologically active compounds from a composition of matter that could contain literally thousands of compounds. Once identified a class of compounds can be purified and concentrated to provide a more effective biological agent. Additionally, the compounds can be chemically modified to provide a composition of matter that is more active and/or less toxic. Finally, once isolated and identified a specific compound or class of compounds can be studied to determine the exact biological activity and mode of action, thus enabling more specific targeting of the compound or class of compounds to treatment of particular diseases or conditions. Contrary to the Examiner's assertion that optimization of factors such as concentration is standard practice, unless one knows what specific compound or class of compounds is exhibiting the desired activity, one cannot possibly optimize the concentration of that compound or class of compounds.

Newmark *et al.* (U.S. Pat. No. 6,387,416), describe an orally or topically administered composition capable of reducing inflammation. With reference to the Table (Specification col. 8-9), the maximum % of baicalin in the formulation described in this patent is approximately the same as the '995 patent discussed above. (20 mg of a 5:1 extract/760 mg total). Additionally, as discussed above Newmark *et al.* neither teach nor suggest the use of free-B-ring flavonoids as COX-2 inhibitors. Newmark *et al.* (U.S. Pat. No. 6,391,346), describe an orally administered composition capable of reducing inflammation in animals. The composition contains 13 extracts, including an extract from the plant *Scutellaria baicalensis*. The only definition of the *Scutellaria baicalensis* root extract provided in the Specification is that it is 5:1, which as noted above, generally refers to 5 parts of plant roots yielding one part of the extract. Also as noted

above, considering that more than 58 compounds have been isolated from *Scutellaria baicalensis*, a hydroalcoholic extract could contain any number of compounds. Additionally, the patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. Therefore, based on the above reasoning, Applicant asserts that none of the cited Newmark *et al.* patents renders the method of the present invention obvious.

Kuhrts (U.S. Pat. No. 6,475,530) describe weight loss compositions that combine a weight loss effective compound and a botanical COX-2 inhibitor. The plant *Scutellaria baicalensis* was referred to in the patent as a COX-2 inhibitor. There is no further description, however, of the material or extract of *Scutellaria baicalensis* being used. Nor is there any reference to amounts or dosage. "*Scutellaria baicalensis*" is the Latin name of a specific species of plant. As a commonly known that different parts of a plant contain totally different types of compounds in different concentrations. To date, there have been more than 58 compounds isolated from various parts of *Scutellaria baicalensis*. The Kuhrts patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. Therefore, for the reasons discussed above, Applicant maintains that the Kuhrts patent does not render the present method obvious.

For the foregoing reasons, Appellant maintains that none of the references cited by the Examiner, either alone or in combination render the present invention obvious and therefore the claims are patentable.

IX. CONCLUSION

In view of the foregoing arguments, Appellant submits that none of the references cited by the Examiner, either alone or in combination anticipate the claims of the instant invention or render the present invention obvious. It is therefore, respectfully requested that the claims be allowed to issue.

Enclosed is a check in the amount of $ 330.00 for the filing of this Appeal Brief. It is believed that no other fees are due with this Appeal Brief. If this is in error, this constitutes a request for any needed extension of time and an authorization to charge all fees therefore to Deposit Account No. 19-5117 if not otherwise specifically requested. In addition, the undersigned authorizes the charge of any additional fees associated with the filing of this document to Deposit Account No. 19-5117.

Respectfully submitted,

Date: December 29, 2003

Rosemary P. Kellogg, #39,726
Swanson & Bratschun, LLC
1745 Shea Center Drive, Suite 330
Highlands Ranch, CO 80129
(303) 268-0066 Telephone
(303) 268-0065 Facsimile

cc: Qi Jia

APPENDIX TO APPELLANT'S BRIEF

The following claims 1, 4, 7, 22, 24-27 and 32-34 are pending in the instant application.

1. A method for inhibiting the cyclooxygenase enzyme COX-2 comprising administering to a host in need thereof a composition comprising 10% to 100% of a mixture of Free-B-Ring flavonoids; wherein said composition is isolated from a plant selected from the Labiatae family, the Scutellaria genus and the *Scutellaria baicalensis* species.

4. The method of claim 1 wherein said Free-B-Ring flavonoids are isolated from a plant part.

7. The method of claim 4 wherein the Free-B-Ring flavonoid is isolated from a plant part selected from the group consisting of stems, stem barks, twigs, tubers, roots, root barks, young shoots, seeds, rhizomes, flowers and other reproductive organs, leaves and other aerial parts.

22. The method of claim 1 wherein the composition of Free-B-Ring flavonoids is administered in a daily dosage selected from 2.0 to 200 mg/kg of body weight.

24. A method for inhibiting the cyclooxygenase enzyme COX-2 comprising administering to a host in need thereof a composition comprised of 10% to 100% of a Free-B-Ring flavonoid; wherein said Free-B-Ring flavonoid is selected from the group consisting of baicalein, 5,6-dihydroxy-7-methoxyflavone, 7,8-dihydroxyflavone and baicalin, wherein said composition is isolated from a plant selected from the Labiatae family, the Scutellaria genus and the *Scutellaria baicalensis* species.

25. The method of claim 24 wherein said Free-B-Ring flavonoid is isolated from a plant part.

26. The method of claim 25 wherein the plant part is selected from the group consisting of stems, stem barks, twigs, tubers, roots, root barks, young shoots, seeds, rhizomes, flowers and other reproductive organs, leaves and other aerial parts.

27. The method of claim 24 wherein the composition of Free-B-Ring flavonoid is administered in a daily dosage selected from 2.0 to 200 mg/kg of body weight.

32. The method of claim 1 wherein said mixture of Free-B-Ring flavonoids contain at least 50% baicalin and baicalein.

33. The method of claim 1 wherein said composition is comprised of 10% to 25% of a mixture of Free-B-Ring flavonoids.

34. The method of claim 24 wherein said composition is comprised of 10% to 25% of a Free-B-Ring flavonoid.

LEXSEE

LINDEMANN MASCHINENFABRIK GMBH, Appellant, v. AMERICAN HOIST AND DERRICK COMPANY, HARRIS PRESS AND SHEAR DIVISION, COMMERCIAL METALS COMPANY, Appellees

Appeal No. 83-1178

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

730 F.2d 1452; 1984 U.S. App. LEXIS 14874; 221 U.S.P.Q. (BNA) 481

March 21, 1984

PRIOR HISTORY: [**1]

Appealed from: District Court for the Southern District of Texas.

DISPOSITION:

REVERSED and REMANDED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant sought review of judgment of the District Court for the Southern District of Texas, sitting without a jury and holding invalid under *35 U.S.C.S. § § 102*(b), 103, and 112, three claims of appellant's patent in appellant's suit against appellees for patent infringement.

OVERVIEW: Appellant sued appellees for patent infringement. Appellees asserted non-infringement and counterclaimed for declaratory judgment that patent was invalid. Lower court ruled patent invalid, and appeal followed. Court held lower court's finding of anticipation under *35 U.S.C.S. § 102*(b) was mistaken and clearly erroneous since its analysis treated claims as mere catalogs of separate parts, in disregard of part-to-part relationship in claims that gave the claims their meaning. Lower court further erred when it viewed statutory presumption of validity, *35 U.S.C.S. § 282,* as "vanished" or "severely weakened" where appellees introduced prior art not cited by examiner; when it reduced required burden of proof to mere preponderance; and when it implicitly required appellant to prove uncited art had been considered by Patent and Trademark Office. Lower court also erred in finding claims' inventions would have been obvious under *35 U.S.C.S. § 103* and in finding patent specification was non-enabling under *35 U.S.C.S. § 112.*

OUTCOME: Court reversed finding that appellant's patent claims were invalid, holding lower court erred in finding inventions set forth in claims was anticipated by another patent, erred in finding invention was obvious, and erred in finding patent specification non-enabling. Case was remanded for lower court to make a finding on infringement.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Patentable Subject MatterPatent Law > Infringement > Burdens of Proof

[HN1] The court's role in relation to patentability does not require it to conclude whether something was or was not invented, or whether the court subjectively considers the invention worthy of patent protection. The court's role is actually more simple. Under the statute, it is to determine whether the patent's challenger carried the burden of establishing invalidity. *35 U.S.C.S. § 282.*

Patent Law > Novelty & AnticipationPatent Law > Jurisdiction & Review > Standards of Review

[HN2] Anticipation is a factual determination, reviewable under the clearly erroneous standard.

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous ReviewPatent Law > Jurisdiction & Review > Standards of Review

[HN3] A finding is clearly erroneous when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.

Patent Law > Novelty & Anticipation
[HN4] Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference.

Patent Law > Infringement > DefensesPatent Law > Infringement > Burdens of Proof
[HN5] The burden upon the challenger of validity under *35 U.S.C.S. § 282* is to introduce evidence of facts establishing invalidity, thus overcoming the presumption. That evidence, if it is to carry the day, must be clear and convincing.

Patent Law > Infringement > DefensesPatent Law > Infringement > Burdens of Proof
[HN6] To the extent that the examiner's consideration of uncited art is material, the burden is on the challenger to show that that prior art had not been considered. The challenger meets that particular burden by showing that the uncited art is more relevant than that cited, just as the patentee defeats the uncited art by showing that its relevancy is equal to or less than that cited.

Patent Law > Novelty & Anticipation
[HN7] The scope of the prior art is defined as that reasonably pertinent to the particular problem with which the inventor was involved.

Patent Law > Statutory BarsPatent Law > Nonobviousness > Tests & Proof of Obviousness
[HN8] A showing of commercial success of a claimed invention, wherever such success occurs, is relevant in resolving the issue of non-obviousness.

COUNSEL:

David Toren, of New York, New York, argued, for Appellant. With him on the brief was Jules Goldberg.

Michael E. Macklin, of Houston, Texas, argued, for Appellees. With him on the brief was Edward W. Goldstein.

JUDGES:

Markey, Chief Judge, Cowen, Senior Circuit Judge, and Bennett, Circuit Judge.

OPINIONBY:

MARKEY

OPINION:

[*1455] MARKEY, Chief Judge.

Appeal from the May 23, 1983, judgment of the District Court for the Southern District of Texas, sitting without a jury and holding invalid claims 1, 2, and 4 of appellant's (Lindemann's) U.S. Patent No. *3,945,315* issued March 23, 1976 and entitled "Hydraulic Scrap Shearing Machine". We *reverse* and *remand.*

BACKGROUND

The Patent

United States Patent No. *3,945,315* (*'315*) issued March 23, 1976 on an application filed April 16, 1975. Peter Dahlem and Hubert Milles are named co-inventors and Lindemann is listed as the assignee. The *'315* patent claims a priority filing date, under *35 U.S.C. § 119,* of May 13, 1974, based on West German application 2423003.

Hydraulic scrap shears, the subject matter of the *'315* patent, [**2] are a principal tool of the scrap metal industry. The shears are large, often weighing several hundred tons, and are designed to cut scrap metal into smaller, uniform pieces for recycling.

There are two basic types of metal processed in the shears: "peddler's scrap" and "rigidly massive scrap".

Peddler's scrap consists of light to medium gauge metal objects, such as light tubing, automobile bodies, and window frames. It makes up a large percentage of the available scrap and is comparatively easy to process.

Rigidly massive scrap consists of heavy gauge metal objects, such as boilers, oil tanks, and railroad cars. Because of thickness or internal reinforcements, massive scrap objects are difficult to process. Traditionally, massive scrap had been processed in very large, tremendously powerful shears, or had been pretreated, e.g., with oxyacetylene torches, to reduce its size or weaken its internal reinforcements. Either approach was costly and time-consuming. Many scrap dealers handled peddler's scrap exclusively.

The Invention

The *'315* patent contains five claims. Claim 1, the only independent claim, is written in Jepson form:

> 1. In a hydraulic scrap-shearing [**3] machine comprising an open feed channel having two opposing side walls, scrap shears at one end of said feed channel and having a mouth narrower than the normal width of said feed channel between said side walls, hydraulic means for moving at least one of said side walls towards the other of said side walls whereby scrap placed in said feed channel can be squashed to a final width no greater than the width of said mouth of said scrap shears, and a feeder ram for pushing scrap along said feed channel into said mouth of said scrap shears, the improvement consisting of said movable one of said side walls being divided into two longitudinal portions of different lengths, and said hydraulic means comprising a main hydraulic ram having a working face forming the longer portion of said movable side wall, and an auxiliary hydraulic ram having a working face forming the shorter portion of said movable side wall just upstream of said mouth of said scrap shears, said auxiliary hydraulic ram being capable of operation independently of said main hydraulic ram.

The claimed structure is shown in Figure 2 of the *'315* patent:

[*1456] [SEE ILLUSTRATION IN ORIGINAL]

In operation, [**4] the combined rams (17, 19) advance into the feed channel (9), crushing and compacting the scrap (12) against the other, non-movable sidewall (14). With peddler's scrap, the two rams move the entire distance together. However, when the channel contains rigidly massive scrap, such as shown at (12), the two rams are quickly brought to a standstill by the scrap's resistence to crushing. The auxiliary ram (19) is then moved forward independently of the main ram (17). The auxiliary ram, having a smaller working surface than the combined rams, is capable of applying a greater crushing force to the scrap. The auxiliary ram cracks and buckles the scrap directly in front of it to crush the leading end of the scrap so it can be pushed through the mouth of the shears. That action also propagates that effect to an adjacent area (H) of the scrap. The structural integrity of the scrap is thus overcome by the auxiliary ram, thereby reducing the resistance of the portion of the scrap in contact with the main ram, allowing both rams to continue forward to crush the scrap to a width less than that of the shear mouth. The feeder ram (11) then pushes the crushed scrap through the mouth of the shear [**5] and under the shear blades (at 5) and clamp (at 6). The clamp holds the crushed scrap in place during cutting.

The claimed invention allows one machine of moderate size to process both peddler's and rigidly massive scrap, and to do so quickly, inexpensively, and without the need for pre-treating massive scrap. Unchallenged testimony described crushing accomplished in minutes of scrap that would have required hours to crush in earlier larger machines and that could not have been crushed without pretreatment.

District Court Proceedings

On October 5, 1980, Lindemann sued appellees (collectively "Amhoist") for infringement of claims 1, 2, and 4 of the *'315* patent. Amhoist asserted non-infringement and counterclaimed for a declaratory judgment that the *'315* patent is invalid.

A three day trial was conducted on June 21-23, 1982. On May 23, 1983, the district court entered FINDINGS OF FACT AND CONCLUSIONS OF LAW, the introduction of which stated:

> After hearing all the evidence the Court concludes that the patent is invalid. Plaintiff simply incorporated two admittedly well-known metal compression features in the same machine and sought to gain a monopoly in the use [**6] of knowledge [*1457] that had previously existed in the public domain. The Court finds and concludes that the claimed invention of the Plaintiff does not meet the statutory or constitutional requirements established for patent protection. Specifically, the machine was an obvious aggregation of prior art which produced no new or synergistic result. It failed materially to promote the progress of science and the useful arts.

The district court entered 60 findings and 20 conclusions indicating its view that the *'315* patent is invalid under *35 U.S.C. § 102*(b), *35 U.S.C. § 103,* and *35 U.S.C. § 112.*

On May 24, 1983 the district court entered judgment declaring the *'315* patent invalid. The judgment is silent respecting infringement, though the district court had stated from the bench at end of trial:

> Well, if the *'315* patent is valid, I think the proof is clear that it has been infringed and it is pretty clear that it was done with

knowledge, conscious knowledge to the point of willful infringement. n1

n1 The district court stated at the same time, "But I am not certain in my own mind at this point whether or not these gentlemen on the *'315* patent invented anything". The statement reflects a misconception of the role of the courts under *35 U.S.C. § 103.* The question mandated by statute is not "invention"; it is *patentability. See Rich, Escaping the Tyranny of Words -- Is Evolution in Legal Thinking Impossible?, 60 JPOS 71,* May-June/APLA Bull. 237 (1978).

Moreover, [HN1] the court's role in relation to patentability does not require it to conclude whether something was or was not "invented", or whether the court subjectively considers the invention "worthy" of patent protection. The court's role is actually more simple. Under the statute, it is to determine whether the patent's challenger carried the burden of establishing invalidity. *35 U.S.C. § 282. See Environmental Designs, Ltd. v. Union Oil Co. of Cal., 713 F.2d 693, 218 USPQ (BNA) 865 (Fed. Cir. 1983), Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 USPQ (BNA) 871 (Fed. Cir. 1983), Rosemount, Inc. v. Beckman Instruments, 727 F.2d 1540 (Fed. Cir. 1984).*

[**7]

Issues

I. Whether the district court erred in finding the inventions set forth in claims 1, 2, and 4 anticipated by U.S. Patent *3,763,770* (*'770*) under *35 U.S.C. § 102*(b).

II. Whether the district court erred in concluding that the inventions set forth in claims 1, 2, and 4 would have been obvious under *35 U.S.C. § 103.*

III. Whether the district court erred in concluding that the *'315* patent specification was non-enabling under *35 U.S.C. § 112.*

IV. Whether this court on remand should order entry of a judgment that claims 1, 2, and 4 were infringed by Amhoist.

OPINION

Of the district court's 60 findings, 57 were those submitted by Amhoist before trial. The source of findings does not render the "clearly erroneous" standard of Fed.R.Civ.P. 52(a) any less applicable or binding. *Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, n.4 (Fed. Cir. 1984).* In adhering firmly to that rule, however, an apparent absence of personal attention need not be disregarded. *See Amstar Corporation v. Domino's Pizza, Inc., 615 F.2d 252, 258, 205 U.S.P.Q. (BNA) 969, 974 (5th Cir. 1980), Wilson v. Thompson, 593 F.2d 1375, 1384 n.16 (5th Cir. 1979).* Under such [**8] circumstances, one court has indicated that strict scrutiny is appropriate. *See Smith International, Inc. v. Hughes Tool Co., 664 F.2d 1373, 215 U.S.P.Q. (BNA) 592 (9th Cir. 1982).* Where, as here, the adopted findings are those proposed by a party *before trial*, a greater chance is created that those findings may be clearly erroneous. Indeed, the present findings include some for which no supporting evidence was submitted at trial.

Having written them, Amhoist argues strenuously for retention of the findings behind the shield of the "clearly erroneous" rule, and repeatedly reminds us of our duty to review the findings favorably and of the burden resting on the appellant. [*1458] However salutary, the rules governing review do not envision an appellate court shirking its duty to reverse an appealed judgment that is clearly based on legal error and unsupported by evidence in the record.

We review judgments, not the rhetoric in opinions. Nonetheless, the language in an opinion, or in a set of findings and conclusions, may indicate that numerous harmful errors of law produced an erroneous conclusion, and that the decisional approach of the district court led to a judgment [**9] not supported in law by the facts of record. That happened here.

I. *Anticipation*

[HN2] Anticipation is a factual determination, reviewable under the "clearly erroneous" standard. *Carman Industries Inc. v. Wahl and Vibra Screw Inc., 724 F.2d 932 (Fed. Cir. 1983), Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 218 U.S.P.Q. (BNA) 781 (Fed. Cir. 1983),* F.R.C.P. 52(a). "A [HN3] finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed". *United States v. U.S. Gypsum Co., 333 U.S. 364, 395, 92 L. Ed. 746, 68 S. Ct. 525, 76 U.S.P.Q. (BNA) 430, 444 (1948); SSIH Equip. S.A. v. USITC, 718 F.2d 365, 381, 218 U.S.P.Q. (BNA) 678, 692 (Fed. Cir. 1983).*

[HN4] Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 U.S.P.Q. (BNA) 193 (Fed. Cir. 1983); SSIH Equip. S.A. v. USITC, 718 F.2d 365, 218 U.S.P.Q. (BNA) 678 (Fed. Cir. 1983).* In deciding the issue of anticipation, the trier of fact [**10] must identify the elements of the claims,

determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman, supra.*

Lindemann contends the district court's finding on anticipation is clearly erroneous and we agree.

The finding of anticipation rested on a series of mistakes. The two gags of the *'770* patent do not correspond to "said sidewall being divided into two portions of different lengths". The gags are beyond the end of the wall and constitute no part of a feed channel sidewall as claimed. The court found the *'770* patent's magazine corresponded to the claimed "open feed channel having two opposing walls", but the "movable" wall of the magazine is movable only to adjust the magazine's width and not, as the claim requires, to crush scrap. Moreover, the findings that the magazine is the feed channel and that the gags are parts of a sidewall of the channel contradict each other. Nor does the shear anvil of the *'770* patent, as the court stated, correspond to the "opposite sidewall" of the claim. Nor do the cylinder assemblies of the *'770* patent move [**11] one sidewall of a feed channel toward the other as the claims require. Nor are the *'770* patent's cylinder and gag (equated by the court to the claimed auxiliary ram) located "just upstream of said mouth". They are within the shear area and are thus downstream from where a mouth narrower than the feed channel would be if the *'770* patent disclosed such a mouth, which it does not. Similarly, the other cylinder and gag of the *'770* patent do not form a "longer portion of said movable sidewall". Nor can the channel that receives rod cuttings after shearing be equated, as did the district court, with the shear mouth claimed. n2

> n2 Amhoist says Lindemann's Australian counsel "conceded" that the *'770* patent cited by the Australian examiner was a "paper anticipation". The assertion is meaningless. First, the *'315* patent's counterpart issued in Australia. Second, the language and laws of other countries differ substantially from those in the United States.

The *'770* patent discloses an entirely different device, [**12] composed of parts distinct from those of the claimed invention, and operating in a different way to process different material differently. Thus there is presented here no possible question of [*1459] anticipation by equivalents. *See Tate Engineering, Inc. v. United States, 201 Ct. Cl. 711, 477 F.2d 1336, 1342, 175 U.S.P.Q. (BNA) 115, 119 (1973).* It is clear, moreover, that the device disclosed in the *'770* patent, had it come after issuance of the *'315* patent, could not be found an infringement of the asserted claims. The district court's analysis treated the claims as mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning.

On the unchallenged evidence of record, we are left with a "definite and firm conviction" that the district court's finding of anticipation was mistaken and therefore clearly erroneous. That part of its judgment relating to invalidity under *35 U.S.C. § 102*(b) must therefore be reversed.

II. *Obviousness*

A. *Presumption of Validity*

Guided by remarks found in then applicable court opinions, the district court: (1) viewed the statutory presumption [**13] of validity, *35 U.S.C. § 282,* as "vanished" or "severely weakened" when Amhoist introduced prior art not cited by the examiner; (2) reduced the required burden of proof, in light of that introduction, to a "mere preponderance" n3; and (3) implicitly required Lindemann to prove that the uncited art had been considered by the PTO.

> n3 The district court in a conclusion of law also stated that "under any burden of persuasion the *'315* patent is invalid because of obviousness". As indicated in the text, we disagree.

(1) Courts are not, of course, at liberty to repeal a statute, or to legislate conditions diminishing its effect. Hence the statutory presumption cannot "vanish" or be "weakened" and the statutorily assigned burden of proof cannot be shifted. *Stratoflex Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 U.S.P.Q. (BNA) 871 (Fed. Cir. 1983).* At the same time, much confusion can be avoided by patentees who refrain from efforts to expand the role of the presumption beyond its burden-assigning and decisional [**14] approach-governing function.

(2) [HN5] The burden upon the challenger of validity under *35 U.S.C. § 282* is to introduce evidence of facts establishing invalidity (thus overcoming the presumption). *American Hoist & Derrick Company v. Sowa & Sons, Inc., 725 F.2d 1350 (Fed. Cir. 1984).* That evidence, if it is to carry the day, must be clear and convincing. *Radio Corp. v. Radio Laboratories, 293 U.S. 1, 79 L. Ed. 163, 54 S. Ct. 752 (1934).* Because the mere introduction of non-considered art (a common phenomenon) does not "weaken" or otherwise affect the presumption, there is no basis for adjusting the required

level of proof downward to a "mere preponderance". That the clear and convincing standard may more easily be met when such non-considered art is *more* pertinent than the cited art means that determination of whether the patent challenger has met its burden turns on the relationship of the uncited art to the claimed invention. *Stratoflex, supra; Railroad Dynamics Inc. v. A. Stucki Co., 727 F.2d 1506 (Fed. Circ. 1984), Solder Removal v. USITC, 65 C.C.P.A. 120, 582 F.2d 628, 199 U.S.P.Q. (BNA) 129 (1978).*

(3) Similarly, the parties have devoted much unnecessary [**15] argument to the question of whether Lindemann is entitled to a presumption that the examiner had considered the uncited art because it is found in the classes and subclasses searched by the examiner (and because, as Lindemann says, the examiner had cited that art in examining an earlier application). Authorities are cited on both sides. n4

n4 The district court indicated the view that "the 'Field of Search' is exactly what it purports to be and nothing more, that 'References Cited' are the patents found within the field which were actually considered by the examiner and listed because he found them to be most relevant". That view is flawed. The examiner could not determine which patents are "most relevant" without considering a number which are less relevant.

Because the touchstone is whether the uncited art is sufficiently more relevant than that cited to serve as evidence of obviousness, argument respecting [*1460] a presumption based on the uncited art's classification is pointless. The argument [**16] here, moreover, appears to have led to the erroneous view that Lindemann bore the burden of proving that the uncited art had been considered. [HN6] To the extent that the examiner's consideration of uncited art is material, the burden is on the challenger to show that "that prior art had *not* been considered." *Richdel Inc. v. Sunspool Corp., 714 F.2d 1573, 219 U.S.P.Q. (BNA) 8 (Fed. Cir. 1983).* The challenger meets that particular burden by showing that the uncited art is more relevant than that cited, just as the patentee defeats the uncited art by showing that its relevancy is equal to or less than that cited. n5

n5 Though the courts will give due respect to the examiner's evaluation of prior art, they are not of course bound thereby. Patentees desiring the benefit of the examiner's evaluation of originally uncited art have available the reexamination procedures under *35 U.S.C. § § 301*-307. Those procedures were not employed in this case.

B. *Scope and Content of the Prior Art* n6

n6 The level of skill is not of record and is not discussed in the briefs.

----------End Footnotes----------

[HN7] - [**17]

"The scope of the prior art has been defined as that 'reasonably pertinent to the particular problem with which the inventor was involved'." *Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 U.S.P.Q. (BNA) 871, 876 (Fed. Cir. 1983)* (and cases cited therein). The district court defined the problem here broadly, i.e., as the problem of compressing waste materials. That finding is clearly erroneous. The inventors' problem was the crushing of massive metal scrap. Nothing in the prior art relied on as invalidating had any relation whatever to the crushing of massive metal scrap.

Lindemann attempts too much in arguing that waste compactors are non-analogous. Though the problems differ, both parties manufacture both products and both are exhibited at the same trade shows. Art that is analogous may or may not render a claimed invention obvious. As indicated below, it does not do so here.

The content of the prior art discussed in Amhoist's brief is that disclosed in the *'770* patent (discussed above) and in British Patent No. 1,230,014 ('014). n7

n7 The district court additionally discussed the S-501 shear produced by Amhoist and incorporating a tapered feed channel with a single side ram about one foot from the shear mouth. Amhoist correctly recognizes on appeal the absence of need to discuss the S-501 shear.

[**18]

The '014 patent discloses a compactor for particulate waste, e.g., garbage. The loose waste is pressed into the wide mouth of a funnel by a circular plate. The smaller end of the funnel communicates with a container to receive the compacted waste. A small finger-like ram is coaxial with, and normally moves with, the plate. When the material fills the funnel so tightly that the plate can add no more, the separately operable small ram can be advanced ahead of the main ram and into the waste material. The small ram has a diameter smaller than that of the funnel outlet. When the small ram has pressed a

core of waste material through the funnel outlet, the remaining waste material is loosened and additional waste material may then be pressed into the funnel by the plate and ram working together.

In a conclusion of law, the district court stated that it had considered the facts in light of the inquiries mandated by *Graham v. John Deere & Co., 383 U.S. 1, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966),* and that a strong indication supporting its conclusion of obviousness was "the fact that three individuals independently created the designs which resulted in development of the split [**19] ram shears which are the subjects of this lawsuit". Because the statute, *35 U.S.C. § 135,* (establishing and governing interference practice) recognizes the possibility of near simultaneous invention by two or more equally talented inventors working independently, that occurrence may or may not be an indication of obviousness when considered in light of all the circumstances. *See E.I. DuPont de* [*1461] *Nemours & Co. v. Berkley & Co., 620 F.2d 1247, 205 U.S.P.Q. (BNA) 1 (8th Cir. 1980).* In this instance, it clearly is not. Two of the three individuals were Dahlem and Milles, the co-inventors listed on the *'315* patent. The third was an Amhoist employee who claimed at trial to have proposed the split ram in January of 1979, more than five years after the invention was made by Lindemann's assignors, nearly three years after the *'315* patent issued, and well after Amhoist's employee Bleeland had in England observed and photographed a Lindemann shear embodying the claimed invention. Accepting, as we must, the district court's crediting of the testimony respecting independent suggestion by an Amhoist employee, that suggestion was simply too late to have been relevant to a determination [**20] of whether the invention would have been obvious at the time it was made, *35 U.S.C. § 103,* which was more than five years earlier.

C. *Commercial Success.*

The district court improperly discounted the weight due the evidence of commercial success because that success occurred abroad. [HN8] A showing of commercial success of a claimed invention, wherever such success occurs, is relevant in resolving the issue of non-obviousness. *Weather Engineering Corp. v. United States, 222 Ct. Cl. 322, 614 F.2d 281, 204 USPQ 41 (1980).*

The evidence at trial showed that the claimed invention accounted for 30% of Lindemann's total sales worldwide for a total sales price of over $20,000,000 (30 machines at approximately $667,000 each). The district court correctly stated that commercial success cannot by *itself* establish nonobviousness. However, having concluded that the claimed invention would have been obvious from the prior art, the court looked only to see whether the showing of commercial success was so overwhelming as to overcome that conclusion. That was error. All evidence must be considered *before* a conclusion on obviousness is reached. *Stratoflex, Inc. v. Aeroquip* [**21] *Corp., 713 F.2d 1530, 218 U.S.P.Q. (BNA) 871 (Fed. Cir. 1983), Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 219 U.S.P.Q. (BNA) 857 (Fed. Cir. 1983), W. L. Gore & Associates v. Garlock, Inc., 721 F.2d 1540, 220 U.S.P.Q. (BNA) 303, 314 (Fed. Cir. 1983).* The commercial success here shown is evidence that the claimed invention was not obvious to those who paid 2/3 of a million dollars for each machine to escape the previously perceived need for pretreatment of massive scrap.

D. *Unexpected Results*

The district court ignored the unexpected or surprising results achieved by the claimed invention. Though no requirement for such results is present in the statute, *35 U.S.C. § 103, Chore-Time Equipment, Inc. v. Cumberland Corp., 713 F.2d 774, 218 U.S.P.Q. (BNA) 673 (Fed. Cir. 1983),* evidence of unexpected results may be strong support for a conclusion of nonobviousness. *Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 219 U.S.P.Q. (BNA) 857 (Fed. Cir. 1983).*

Neither the district court nor Amhoist's brief on appeal has a word to say about the unexpected results asserted by Lindemann, namely, the rapid crushing of rigidly massive scrap in a moderate sized scrap shear without [**22] pretreatment. That the claimed inventions achieve those results is unchallenged. Neither the district court nor Amhoist suggest anything in any piece of prior art, or in the prior art as a whole, that would lead one skilled in the art to expect achievement of such results.

The record is clear that no earlier shears of any size, and no prior art device of any type could economically process rigidly massive scrap without pretreatment. Unchallenged testimony of experts was characterized by surprise and amazement that the claimed invention was able to accomplish that feat. That it could do so in minutes, and with a moderate sized structure, were further sources of surprise. That those skilled in the art had previously believed pretreatment of rigidly massive scrap was required was also uncontradicted.

[*1462] It is further clear from the uncontradicted evidence that the claimed invention achieved new and unexpected results nowhere suggested in the prior art, and that the district court overlooked the effect of that achievement in reaching its determination of obviousness. In so doing, the district court erroneously focussed its inquiry "solely on the product created, rather

[**23] than on the obviousness or nonobviousness of its creation". *General Motors Corp. v. U.S. International Trade Commission, 69 C.C.P.A. 116, 687 F.2d 476, 482-83, 215 U.S.P.Q. (BNA) 484, 489 (1982).*

The district court viewed the claimed invention as merely the "aggregation" of two different sized rams. Finding the first in one place in the prior art and the second in another place, the district court entered this conclusion:

> Plaintiff simply put the two features in the same machine and connected them as was necessary depending on whether the scrap was small or large. It used a known connection idea. The *'315* machine possessed one known feature to operate in a known way to produce a known result to deal with the first scrap situation and another known feature operating in a known manner to produce a known result to deal with the second. Clearly, this was an obvious solution using already appreciated or obvious features to solve the problem of how to develop a machine that could handle both types of scrap most economically.

The *'315* patent specifically stated that it disclosed and claimed a combination of features previously used in two separate devices. That [**24] fact alone is not fatal to patentability. The claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. *In re Imperato, 486 F.2d 585, 179 U.S.P.Q. (BNA) 730 (CCPA 1973); In re Sernaker, 702 F.2d 989, 217 U.S.P.Q. (BNA) 1 (Fed. Cir. 1983).* That question must here be answered in the negative.

Nothing in the references alone or together suggests the claimed invention as a solution to the problem of crushing rigidly massive scrap. There was nothing whatever of record, therefore, to support the district court's statement that the claimed machine possessed "another known procedure operating in a known manner to produce a known result" or its conclusion that Lindemann "knew . . . that a small sidewall ram could most economically process large scrap".

The '014 patent deals only with soft, easily compactible, particulate material. Though that patent discloses a two-ram structure and the principle that loose material when too tightly compacted can be loosened by injection of a thin ram into the material, the claims here are not drawn [**25] to the mere concept of two differently sized rams, or to the known principles governing the effects of large and small rams (or to the propagation of force principle discussed at trial). That the claimed invention may employ known principles does not in itself establish that the invention would have been obvious. Most inventions do. Nothing in the '014 patent would suggest that rigidly massive scrap could be rapidly and economically crushed and sheared without pretreatment.

The *'770* patent, as above indicated, deals only with holding brittle material within a shear by compression. Nothing in the *'770* patent suggests that making the crushing wall of a metal scrap shear in two independently operable parts, with a smaller part adjacent the mouth of the shears, would enable the crushing of massively rigid scrap without pretreatment.

Nothing, moreover, in the '014 or *'770* patents adds anything to the prior art considered by the examiner. As above indicated, the *'315* specification itself recognized the separate presence in the prior art of feed channels with one solid moveable crushing wall and of feed channels with a small ram in one of two fixed sidewalls. The examiner cited [**26] as "of interest" the Pioch patent which, like the '014 patent, [*1463] disclosed two independently operable pushers in a waste compactor.

Applying the standard of Rule 52(a), Fed. R. Civ. P., we are persuaded that the findings underlying the district court's conclusion of obviousness are clearly erroneous. Further, that conclusion resulted from errors of law in interpreting the claims and in consideration and application of the prior art. That part of the appealed judgment relating to *35 U.S.C. § 103* must therefore be reversed.

III. *Enablement*

The district court concluded that the *'315* patent was non-enabling because it did not disclose a hydraulic and electrical system for controlling the operation of the rams.

Enablement is a legal issue. *Raytheon Co. v. Roper Corp., 724 F.2d 951 (Fed. Cir. 1983).* The question is whether the disclosure is sufficient to enable those skilled in the art to practice the claimed invention, hence the specification need not disclose what is well known in the art. *In re Myers, 56 C.C.P.A. 1129, 410 F.2d 420, 161 U.S.P.Q. (BNA) 668 (1969).*

The unchallenged evidence of record establishes that hydraulic and electrical systems [**27] for metal scrap shears were well known to those skilled in the art, and that the selection and connection of the elements of such systems was simply a matter of plumbing.

Amhoist points to testimony relating to 800 man hours it expended in developing its split ram shear. It also points to the dismantling of the accused machines by its two customers, whereby the rams are operated together as one sidewall and asserts that the split ram structure of the claimed invention has thus been abandoned by those customers. n8 There is no evidence indicating that the dismantling was due to difficulty in designing a suitable hydraulic-electric control system.

n8 The record does not reflect the rationale underlying a vigorously fought lawsuit and its accompanying expense in the light of two sales and both purchasers' cessation of use of the invention.

It is clear that no undue experimentation was required in practicing the claimed invention. *W.L. Gore & Assoc. Inc. v. Garlock, Inc., 721 F.2d 1540, 1557, 220 USPQ* [**28] *(BNA) 303, 316 (Fed. Cir. 1983).* Amhoist spent approximately 100 more hours than did Lindemann in designing the entire split ram shear, including the hydraulic-electric control system. There was no evidence of the amount of time needed to develop the control system itself. Of the total time Amhoist spent on developing its shear, it devoted an undisclosed amount attempting to create a "hydraulically operated pin" to connect the two rams. That pin was unnecessary. The *'315* patent's specification discloses a simple mechanical pin to achieve the same connection. Further, Amhoist conceded at oral argument that nothing in the claims fails of enablement in the specification.

The district court erred in its conclusion that the *'315* patent specification is non-enabling and that part of the appealed judgment relating to *35 U.S.C. § 112* must be reversed.

IV. *INFRINGEMENT*

Relying on the statement made by the district court at close of trial, and on the uncontested evidence clearly establishing Amhoist's knowledge of the *'315* patent and its conscious decision to disregard it, Lindemann requests this court to "affirm" the district court's "decision" on infringement. Lindemann's [**29] difficulty is that judgments, not statements, are appealed and the district court made no finding and entered no judgment on infringement.

A district court should decide validity and infringement and should enter a judgment on both issues when both are raised in the same proceeding. *Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 U.S.P.Q. (BNA) 871 (Fed. Cir. 1983).* To enter judgment on less than all dispositive issues can be inefficient, risking as it does the necessity of the district court and the parties [*1464] undertaking participation in another long and costly proceeding.

The case must be remanded for the district court to make a finding on infringement. Whether the present record supports a finding corresponding with the court's end-of-trial statement, and whether further trial on the issue is therefore unnecessary, is for the district court to determine in the first instance. Upon any finding of infringement and entry of judgment on that finding, the district court will doubtless consider issuance of an injunction against further infringement and an accounting.

DECISION

The district court's judgment is reversed and the case is remanded for further [**30] proceedings consistent with this opinion.

REVERSED and REMANDED

LEXSEE

ALCO STANDARD CORPORATION, an Ohio corporation, Appellee, v. TENNESSEE VALLEY AUTHORITY, a U.S. corporation, and WESTINGHOUSE ELECTRIC CORPORATION, a Pennsylvania corporation, Appellants

No. 85-2420

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

808 F.2d 1490; 1986 U.S. App. LEXIS 20930; 1 U.S.P.Q.2D (BNA) 1337

December 30, 1986, Decided

PRIOR HISTORY: [**1]

Appealed from U.S. District Court for the Western District of Tennessee, Judge Horton.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellants, a United States corporation and its indemnitor, appealed a judgment of the United States District Court for the Western District of Tennessee, holding appellee corporation's patent covering a method of and apparatus for inspecting turbine rotors valid and infringed.

OVERVIEW: Appellee corporation held a patent covering a method of and apparatus for inspecting turbine rotors. Appellee alleged that appellants, a United States corporation and its indemnitor, were liable for patent infringement, and the district court agreed. The court affirmed, holding that it had jurisdiction under *28 U.S.C.S. § § 1295*(a)(1) and 1338(a) to hear the appeal, since the district court exercised its jurisdiction on the basis of an Act of Congress "relating to patents." Furthermore, the district court properly ruled that the invention of appellee's patent was not obvious, where strong evidence of secondary considerations established that the invention, which appeared to have been obvious in light of the prior art, was not. Specifically, the invention was a commercial success that fulfilled long-felt but unresolved needs in a field where others had failed. Although the evidence of infringement was circumstantial, such evidence was not any less credible or persuasive.

OUTCOME: The court affirmed the district court's judgment that the claims of appellee's patent were valid and enforceable and that appellants were liable for infringement of those claims, since appellants did not show that the district court's findings were clearly erroneous, and the district court's errors were harmless.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction
[HN1] Under *28 U.S.C.S. § § 1295*(a)(1) and 1338(a), the United States Court of Appeals for the Federal Circuit has jurisdiction over an appeal from a district court if the jurisdiction the district court exercised was based upon an Act of Congress "relating to patents."

Patent Law > Jurisdiction & Review > Standards of Review
[HN2] The reviewing court's role is to determine whether the district court committed any reversible errors, either in its factual findings or in its legal conclusions or rulings, not to decide the case de novo.

Patent Law > Specification & Claims > Enablement RequirementPatent Law > Specification & Claims > Description Requirement
[HN3] See *35 U.S.C.S. § 112.*

Patent Law > Originality > Joint & Sole Inventions
[HN4] The inclusion in a patent of a process that may be performed by a person, but that also is capable of being performed by a machine, is not fatal to patentability.

Patent Law > Novelty & Anticipation
[HN5] Under *35 U.S.C.S. § 102*(a), a patent is invalid if the invention was described in a printed publication in the United States before the invention thereof by the applicant for patent. Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.

Patent Law > Nonobviousness > Tests & Proof of ObviousnessPatent Law > Infringement > DefensesPatent Law > Infringement > Burdens of Proof
[HN6] The existence of uncited prior art more relevant or more pertinent than the art called to the attention of the Patent Office does not weaken the statutory presumption that a patent is valid pursuant to *35 U.S.C.S. § 282*. It merely makes it easier for the party challenging the validity of the patent to carry his burden of proof.

Patent Law > Infringement > DefensesPatent Law > Infringement > Burdens of Proof
[HN7] The presumption of a patent's validity may be rebutted only by clear and convincing evidence.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN8] The criteria for determining obviousness are (i) the scope and content of prior art, (ii) differences between the claims of a patent and the prior art, and (iii) the level of ordinary skill in the pertinent art. Secondary considerations relating to obviousness include commercial success, long-felt but unsolved needs, and failure of others.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN9] In evaluating the scope and content of prior art and the differences between that art and the claims of a patent, the question is not simply whether the prior art "teaches" the particular element of the invention, but whether it would suggest the desirability, and thus the obviousness, of making the combination.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN10] Prior art cannot be evaluated in isolation, but must be considered in the light of the secondary considerations bearing on obviousness.

Patent Law > Infringement > Acts of Infringement
[HN11] Although evidence of infringement may be circumstantial, that does not make it any less credible or persuasive.

COUNSEL:

John F. Lynch, for Appellants. With him on the brief was Alan H. Gordon.

Gomer W. Walters, for Appellee. With him on the brief were Rolf O. Stadheim, John W. Hofeldt.

JUDGES:

Friedman, Rich, and Nies, Circuit Judges. Nies, Circuit Judge, concurring. Rich, Circuit Judge, dissenting.

OPINIONBY:

FRIEDMAN

OPINION:

[*1492] FRIEDMAN, Circuit Judge.

This is an appeal from the judgment of the United States District Court for the Western District of Tennessee, *597 F. Supp. 133,* in a patent infringement suit holding U.S. Patent No. *3,960,006* (*'006* patent) valid and infringed. The case was tried to the court, which decided only the liability and not the damages issue. We affirm.

The plaintiff below and the appellee here is Alco Standard Corporation (Alco), which acted through its Commercial Machine Works division (Commercial). The nominal defendant below and an appellant here is the Tennessee Valley Authority (TVA). The defendant real party in interest is the third party defendant, and co-appellant here, Westinghouse Electric Corporation (Westinghouse), which performed [**2] services involving the patented invention for TVA and agreed to indemnify TVA for any damages arising from those services.

Prior to trial, the court dismissed Alco's patent infringement claims against Westinghouse. *Alco Standard Corp. v. Tennessee Valley Authority, 448 F. Supp. 1175 (W.D. Tenn. 1978).* Westinghouse remained in the case, as the indemnitor of TVA, and has conducted the defense of this suit.

I

Background

A. The *'006* patent covers a method of and apparatus for inspecting turbine rotors in electrical generators by the use of ultrasonic waves to detect discontinuities within the rotors. Discontinuities are cracks, flaws, or impurities and may result when the rotors are made or may develop later with use. Turbine rotors are large cylindrical metal forgings which can be

as long as 30 feet and weigh as much as 100 tons. In operation, they may rotate at speeds as high as 3600 revolutions per minute and reach temperatures of 1000 degrees F. The high speeds and temperatures subject the rotor to stress, so that discontinuities in the turbine forging may cause it to fly apart.

As early as 1946, turbine rotor forgings were being inspected with ultrasonic [**3] tests. Such tests were performed from the outside of the forgings of newly manufactured rotors. In 1957, Westinghouse undertook a development program to improve its ultrasonic inspections. In 1959, Westinghouse discovered that General Electric Corporation was producing a new type of ultrasonic inspection, a boresonic testing device, that could be inserted into the bore of the rotor as distinguished from prior inspection devices that scanned only the outside of the rotor. Upon learning this, Westinghouse abandoned its development program, purchased the General Electric device and used it until 1972. The General Electric device, although providing for a bore inspection, could be used to inspect only newly manufactured rotors.

In the 1950's it became clear that a system for inspecting rotors that were not newly manufactured was needed because such rotors otherwise had to be removed from the turbine and shipped to the inspection site, causing costly delays. Apparently, General Electric solved this problem, and Westinghouse attempted to buy the new General Electric device in 1972. General Electric, however, refused to sell the new device, and therefore Westinghouse again began its own [**4] independent development program, this time to produce an on-site inspection device. Westinghouse's development of an on-site inspection device did not go as planned, and soon fell behind schedule.

[*1493] Also during 1972, Mr. Smith, an employee of Commercial, conceived the idea of producing a new type of boresonic test apparatus. In December 1972, Westinghouse officials, including a Mr. Ronca, visited Commercial to discuss Commercial's idea for such an apparatus. At that meeting, Mr. Ronca stated that he thought that Commercial's concept was not feasible because Westinghouse's own research and development in that area had been unsuccessful. Despite Westinghouse's skepticism, Commercial contracted to have the boresonic unit constructed.

In January 1974, Commercial demonstrated its boresonic device to Westinghouse. Among those Westinghouse representatives in attendance was Mr. Ronca, who, after witnessing the demonstration, wrote that the "system represent[ed] a significant advancement in the field of boresonics. . . ." Based on the Commercial demonstration, Westinghouse discontinued its research on boresonic devices and pursued the possibility of purchasing Commercial's [**5] device.

In mid-1974, a rotor in TVA's Gallatin steam plant exploded, causing substantial property damage and, luckily, no bodily injuries. Commercial inspected the remaining rotor at the Gallatin plant and discovered that it had a discontinuity similar to the one that caused the first rotor to explode. Subsequent remedial measures were taken to remove the discontinuity in the remaining rotor.

By October 1974, Westinghouse had abandoned its plan to purchase Commercial's boresonic units and had begun developing its own boresonic unit. It developed such a unit. Alco alleged that Westinghouse infringed the *'006* patent by using the Westinghouse device in inspecting TVA rotors.

B. The invention the *'006* patent covers was made by Robert Smith when he was an employee of Commercial. The patent issued on June 1, 1976, and was assigned to Alco.

In the present suit, Commercial alleged infringement of six claims of the *'006* patent. Three of these are apparatus claims and the other three are method claims.

Claim one, the broadest apparatus claim, is directed to a device for detecting discontinuities in a turbine rotor. The device has a probe that is inserted into the bore of a turbine [**6] rotor. Attached to this probe is an indexing means that determines the position of the probe within the rotor. The probe, itself, contains at least two ultrasonic sources (called "transducers") that simultaneously can send ultrasonic signals into the rotor. Any signals sent into the rotor that are reflected back to the probe are picked up by an ultrasonic pickup and recorded in such a manner that the "existence, position, nature, size and shape of the flaws in the rotor" can be determined.

The method claims generally describe a method for determining flaws within turbine rotors that utilizes the device described in the apparatus claims.

The claims are discussed in greater detail later in this opinion.

C. In a lengthy opinion, the district court held that the *'006* patent was valid and that Westinghouse had infringed the patent in using its own boresonic device to inspect TVA rotors. Specifically, the district court ruled that the Commercial invention was novel under *35 U.S.C. § 102* and non-obvious under *35 U.S.C. § 103*. The court also thoroughly examined whether Commercial had complied with the enabling, description, and definiteness [**7] requirements of *35 U.S.C. § 112* and found that it had. Regarding infringement, the

district court found that the "Westinghouse device contain[ed] every element found in claims 1, 2, 3, 7, 8 and 10 of the *006* patent."

II

Jurisdiction

[HN1] Under *28 U.S.C. § 1295*(a)(1) (1982), we have jurisdiction over this appeal from the district court if its jurisdiction "was based, in whole or in part, on section 1338 of this title . . . ." Section 1338(a) gives the [*1494] district courts "jurisdiction of any civil action arising under any Act of Congress relating to patents . . ." The inquiry thus is whether the jurisdiction the district court exercised in this case was based upon an Act of Congress "relating to patents."

The Tennessee Valley Authority Act of 1933 contains a specific provision dealing with patents. Section 831r of title 16 (1982) is captioned "Patents; access to Patent and Trademark Office and right to copy patents; compensation to patentees." It gives the Tennessee Valley Authority (TVA) access to the Patent and Trademark Office [**8]

> for the purpose of studying, ascertaining, and copying all methods, formulae, and scientific information (not including access to pending applications for patents) necessary to enable [TVA] to use and employ the most efficacious and economical process for . . . any method of improving and cheapening the production of hydroelectric power.

It then provides that

> any owner of a patent whose patent rights may have been thus in any way copied, used, infringed, or employed by the exercise of this authority by [TVA] shall have as the exclusive remedy a cause of action against [TVA] to be instituted and prosecuted on the equity side of the appropriate district court of the United States, for the recovery of reasonable compensation for such infringement.

The statute, in the second quoted passage, thus recognizes that the use by TVA of a patented invention constitutes infringement of the patent. Although the statute specifies that the patentee's "exclusive remedy" if its patent has been "thus . . . infringed . . ." is a civil suit against TVA on the equity side of the district court to recover "reasonable compensation for such infringement," that [**9] fact does not make the resulting suit any the less one for infringement of a patent. Thus, § 831r specifies the conditions that govern the patentee's suit for infringement, while § 1338(a) gives the district courts jurisdiction to hear that suit.

It would be anomalous if appeals in patent infringement suits against TVA were heard by the regional circuit, when all other appeals in patent infringement suits come to this court. (We have exclusive jurisdiction over appeals from the district courts in patent infringement suits generally, and over appeals from the Claims Court in suits for patent infringement against the United States, over which the Claims Court has exclusive jurisdiction under *28 U.S.C. § 1498*(a). *28 U.S.C. § 1295*(a)(1), (3).) Such a bifurcated jurisdiction would be inconsistent with the Congressional intent in enacting the Federal Courts Improvement Act of 1982 to "produce desirable uniformity in this area of the law." S. Rep. No. 275, 97th Cong., 2d Sess. 5 (1982), *reprinted in* 1982 U.S. Code Cong. & Ad. News 11, 15. There is no reason to believe that Congress intended the regional circuits rather than this court [**10] to hear appeals in this narrow category of infringement cases.

The earlier decision of the district court in this case, dismissing the suit against Westinghouse, is not inconsistent with this conclusion. The ground of that decision was that under *16 U.S.C. § 831r,* the patentee had no cause of action against Westinghouse because its "exclusive remedy with regard to the inspections for TVA is the claim for reasonable compensation asserted against TVA in this cause under Section [831r]." *Alco Standard Corp. v. TVA, 448 F. Supp. 1175, 1181, 197 U.S.P.Q. (BNA) 671, 675 (W. D. Tenn. 1978).*

The earlier decision did not hold that the jurisdiction of the district court in this case was based upon any statute other than *28 U.S.C. § 1338*(a). The district court began both that opinion and its later opinion on the merits by describing this suit as "a patent infringement action" and an "action for patent infringement," respectively. Although the district court's characterization of the case does not bind us, we see no reason to reject it. In sum, the district court action in this case arose under an [*1495] "Act of Congress [**11] relating to patents," and we therefore have jurisdiction over the appeal.

III

Validity of the '006 Patent

In challenging the district court's determination that the *'006* patent is valid, the appellants mount a broad scale but largely unfocused attack upon the sufficiency of the evidence to support the district court's factual

findings upon which its conclusion of validity rests. In effect, the appellants invite us to decide the case *de novo*. That is not our function, however; [HN2] our role is to determine whether the district court committed any reversible errors, either in its factual findings or in its legal conclusions or rulings. *Raytheon Co. v. Roper Corp., 724 F.2d 951, 956, 220 U.S.P.Q. (BNA) 592, 596 (Fed. Cir. 1983), cert. denied, 469 U.S. 835, 105 S. Ct. 127, 83 L. Ed. 2d 69 (1984).* The scattered and disorganized nature of the appellants' presentation has made the performance of our reviewing role more difficult.

In this appeal we do not specifically deal with the myriad of minor contentions that the appellants make, although we have [**12] considered them. Here we address only the major issues the parties have presented.

A. *The Enabling and Description Requirements (35 U.S.C. § 112 (1982)).*

The first two paragraphs of [HN3] *35 U.S.C. § 112* provide:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The district court ruled that the *'006* patent met the requirements of section 112. The court found that "one skilled in the art of ultrasonic testing could have determined how to make and use the patented invention from reading the patent specification, [**13] " that "the specification does adequately describe the claimed invention" because "evidence established one skilled in the pertinent part would be aware of the various methods and various equipment that could be used to obtain and record the [ultrasonic] data generated by the invention's transducers," and that the specification of the *'006* patent "supported" the claim. The district court further ruled that "after weighing all the evidence, the Court finds defendants have not proved the patented device was not able to achieve the results claimed in the patent."

On appeal, the contentions of both parties center around the language of the claims that pertains to correlating and combining the information derived from the ultrasonic scans. Claim 1 covers a "non-destructive test apparatus for detecting and providing three-dimensional analysis of flaws in a horizontally positioned generally cylindrical rotor" comprising, among other elements,

> position determining means providing for the direct correlation of the information content of a transmitted or reflected ultrasonic signal in one mode with the information content of reflected ultrasonic signals and unreflected transmitted [**14] ultrasonic signals in another mode,

and

> recording means for preserving the information content of said transmitted and said reflected ultrasonic signals in a fashion that permits combining the individual information content of each of said transmitted and said reflected ultrasonic signals in the different modes to derive an accurate indication of the existence, position, nature[,] size and shape of flaws in the rotor material.

The prosecution history of the *'006* patent demonstrates that the words "correlating" and "combining" have specific and [*1496] definite meanings, which one skilled in the art of the invention would have understood.

The word "correlate" as used in the *'006* patent refers to the steps of (1) taking the raw data from the ultrasonic scans in the various modes, (2) calculating the position of the defects -- circumferentially, longitudinally, and axially -- by using the angle of the probe, its depth into the rotor and the time it took for the ultrasonic pulse to be reflected back off the defects (flight time), and (3) grouping those calculated positions with others in the same general area. This grouping is necessary because [**15] a single defect may generate more than one ultrasonic blip (reflected ultrasonic pulse) during an entire test run due to the spread of ultrasonic beams and the use of multiple transducers. In the *'006* patent, to correlate means to group together all the ultrasonic blips that correspond to the same defect.

The word "combine" as used in the *'006* patent refers to gathering all the ultrasonic blips that have been correlated for one defect and using those blips to derive

information about the nature of the defect that any single blip might not have revealed. The inventor, speaking through his attorney, described "combining" best in an amendment filed with the Patent Office on October 19, 1975:

> Suppose that a pair of parallel cracks existed at the same angle with respect to the axis of the rotor as that followed by the shear waves, with the ends of these cracks overlapping but spaced apart. Testing with a straight [longitudinal] beam would show the presence of the two cracks, but would be unable to determine if the cracks were connected. On the other hand, testing with a shear wave would provide no signal at all. Therefore, this lack of any indication by the shear wave test [**16] would provide no information at all without combining the results of this test with the results of the longitudinal mode test, such combination revealing the existence of two separate cracks rather than a single connected crack.

The district court's holding that one skilled in the art would have known how to correlate and combine the ultrasonic scan data from a reading of the patent disclosure is not erroneous. *Raytheon, 724 F.2d at 960, 220 USPQ at 599.*

The appellants also contend that the correlating and combining steps of the *'006* patent are merely mental processes, and therefore, unpatentable. Under the meaning of correlating and combining used in the patent, these steps may be performed either by a person or by a machine. The record shows that the scan data are arranged and grouped using simple trigonometric calculations and graphic techniques. Any mental processes occur after the data has been subjected to calculation and graphing.

[HN4] The inclusion in a patent of a process that may be performed by a person, but that also is capable of being performed by [**17] a machine, is not fatal to patentability. *Diamond v. Diehr, 450 U.S. 175, 67 L. Ed. 2d 155, 101 S. Ct. 1048 (1981).* The presence of the steps of correlating and combining, which a machine is capable of doing, does not invalidate the *'006* patent.

B. *Anticipation (35 U.S.C. § 102(a) (1982)).*

[HN5] Under *35 U.S.C. § 102*(a), a patent is invalid if "the invention was . . . described in a printed publication in this . . . country . . ., before the invention thereof by the applicant for patent." We have held that "anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W. L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1554, 220 U.S.P.Q. (BNA) 303, 313 (Fed. Cir. 1983).* This is essentially the same standard the district court applied when it cited *American Seating Co. v. National Seating Co., 586 F.2d 611, 618, 199 U.S.P.Q. (BNA) 257, 261 (6th Cir. 1978), cert. denied, 441 U.S. 907, 99 S. Ct. 1999, 60 L. Ed. 2d 377, 202 U.S.P.Q. (BNA) 320 (1979),* [**18] which stated that "all the elements of a patented device . . . be found in a single pre-existing structure or description" (citations omitted).

[*1497] The appellants contended in the district court, and repeat the contention here, that a publication entitled "Ultrasonic Inspection of the Nimrod Power Plant" (Nimrod), which described a method and device for boresonically inspecting a rotor, anticipated the *'006* device patent. The district court held that the Nimrod publication did not anticipate the *'006* patent because there were three elements in the *'006* patent that were not disclosed in the Nimrod article:

1. "the Nimrod device does not teach simultaneous scanning with multiple transducers . . .";

2. "the Nimrod article . . . does not teach combining or correlating the information content of ultrasonic signals from the various modes"; and

3. "the Nimrod device . . . does not rotate around the internal circumference of the bore . . . ."

The district court did not specify which claims of the *'006* patent include the three elements that it found were not disclosed in the Nimrod article or whether each of the six disputed claims before us contains those three elements. [**19] In order to determine the correctness of the district court's findings of non-anticipation, therefore, a detailed comparison of the claims with the Nimrod article is necessary. The appellants have conceded that the Nimrod article does not anticipate claims 1, 2, and 3 of the *'006* patent:

> The *Nimrod* article is *anticipatory* of method claims 7, 8 and 10. *Nimrod* differs from apparatus claims 1-3 in that only a single mode transducer at a time was placed upon the Nimrod probe so that "simultaneous transmission of signals in various modes is not disclosed.

An examination of these claims, therefore, is not necessary. A comparison with the method claims, though, shows that each claim has at least one element not disclosed in the Nimrod article.

Claim 7 is directed at ultrasonic inspection. It includes the step of "combining the information [from the ultrasonic signals] to derive an accurate indication of the position, nature, size and shape of the flaws in the rotor material." Although the Nimrod article discloses three means for recording the output of the ultrasonic detector (Mk. VI flaw detector display unit, two channel flaw alarm unit, and an auxiliary [**20] display unit for "photographic recording purposes"), these recording means do not permit the combining of information.

Claim 8 describes in more detail the method described in claim 7. It includes the combining element of claim 7 not shown in the Nimrod article.

Claim 10, which depends upon claim 8, similarly contains the combining element of claim 7 that makes the Nimrod article not anticipatory.

In sum, claims 7, 8, and 10 are not anticipated by the Nimrod article. The district court's finding to that effect is not clearly erroneous. *Carman Industries, Inc. v. Wahl, 724 F.2d 932, 220 U.S.P.Q. (BNA) 481 (Fed. Cir. 1983).*

C. *Obviousness (35 U.S.C. § 103).*

1. The district court recognized the statutory presumption that a patent is valid *(35 U.S.C. § 282* (1982)). It ruled that the presumption of validity is weakened if there is prior art that is more pertinent than the art called to the attention of the Patent Office. It then concluded, however, that the "defendants did not present any evidence demonstrating why the art not cited to the patent office was more relevant or more pertinent than the art cited [**21] to the patent examiner, and the Court has found no ground for such a conclusion," and that the presumption of validity had not been weakened.

We have repeatedly held that [HN6] the existence of such uncited prior art does not weaken the presumption but merely makes it easier for the party challenging the validity of the patent to carry his burden of proof. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 U.S.P.Q. (BNA) 481 (Fed. Cir. 1984); Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 221 U.S.P.Q. (BNA) 669* (Fed. Cir.), *cert. denied, 469 U.S. 857, 105* [*1498] *S. Ct. 187, 83 L. Ed. 2d 120 (1984); Lear-Siegler, Inc. v. Aeroquip Corp., 733 F.2d 881, 221 U.S.P.Q. (BNA) 1025 (Fed. Cir. 1984).* The court's error in dealing with the effect of prior uncited art upon the presumption was harmless, however, in view of the court's holding that there was no prior art more pertinent than that called to the attention of the Patent Office. *Cf. Stratoflex Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534, 218 U.S.P.Q. (BNA) 871, 876 (Fed. Cir. 1983).* [**22]

The district court also erred in ruling that the presumption of validity could be overcome by a preponderance of the evidence. [HN7] The presumption may be rebutted only by clear and convincing evidence. *Jones v. Hardy, 727 F.2d 1524, 220 U.S.P.Q. (BNA) 1021 (Fed. Cir. 1984).* This error also was harmless, however, since the district court found that the appellants had not met the less exacting burden of proof the district court applied.

Portions of the district court's opinion do not focus upon the language of the claims of the *'006* patent -- both in comparing that patent with the prior art in determining obviousness and later in comparing it with the Westinghouse device in determining infringement -- but more broadly refer to the "patent" itself. Other portions of the opinion, however, indicate that the district court's comparisons were based upon the language of the claims. Our review of the record satisfies us that the district court's conclusion of nonobviousness was correct, and that its findings of infringement, discussed later, were not clearly erroneous.

2. In holding [**23] that the invention of the *'006* patent would not have been obvious to one of ordinary skill in the art at the time the invention was made, the district court applied [HN8] the criteria for determining obviousness announced in *Graham v. John Deere, 383 U.S. 1, 17-18, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966).* The court determined (i) the scope and content of [the] prior art," (ii) "differences between the *'006* claims and the prior art," and (iii) "the level of ordinary skill in the pertinent art." The court also discussed at length the "secondary considerations" relating to obviousness, including commercial success, long-felt but unsolved needs, and failure of others, an inquiry we have held is an essential and integral part of determining obviousness *vel non. Jones v. Hardy, 727 F.2d 1524, 220 U.S.P.Q. (BNA) 1021 (Fed. Cir. 1984); Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 220 U.S.P.Q. (BNA) 97 (Fed. Cir. 1984); Simmons Fastener Corp. v. Illinois Tool Works, Inc., 739 F.2d 1573, 222 U.S.P.Q. (BNA) 744 (Fed. Cir. 1981),* [**24] *cert. denied, 471 U.S. 1065, 105 S. Ct. 2138, 85 L. Ed. 2d 496 (1985).*

In determining the ordinary level of skill in the art, the district court found that Gilbert Ronca, a Westinghouse employee, was one of such skill. The appellants accuse the district court of not having made an adequate level-of-skill determination. We cannot say, however, based upon what the district court stated and what the record shows about Mr. Ronca's qualifications and his background and experience in the industry, that the district court's finding that the ordinary level of skill in the art was that of Mr. Ronca was clearly erroneous and did not constitute an adequate level-of-skill determination.

In evaluating the scope and content of the prior art and the differences between that art and the claims of the *'006* patent, the district court erred in concluding that "none of the prior art not cited to the patent office teaches combining the information content of the various modes of reflected and unreflected signals, as does the *'006* patent." U.S. Patent No. *3,221,544* (Gunkel), not cited to the Patent Office, discloses an electrical method for combining data from multiple ultrasonic [**25] scans. Moreover, [HN9] the question is not simply whether the prior art "teaches" the particular element of the invention, but whether it would "suggest the desirability, and thus the obviousness, of making the combination." *See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. (BNA) 543, 551 (Fed. Cir. 1985); Lindemann Maschinenfabrik GMPH v. American Hoist & Derrick, 730 F.2d 1452, 1462, 221 U.S.P.Q. (BNA) 481, 488 (Fed. Cir. 1984).*

[*1499] The district court described the Gunkel patent as a device which "detect[s] and analyze[s] defects in tubular articles such as pipes. The device inspect[s] pipes from the outer diameter. Multiple transducers transmit[] ultrasonic signals as the pipe [is] rotated spirally past the patented device." Although this statement was correct, the district court failed to recognize that the Gunkel device could electrically combine signals from multiple transducers.

The Gunkel patent is directed to an ultrasonic inspection system containing a "novel means for analyzing defect signals to [**26] determine the character of the defect." The Gunkel patent describes two methods of utilizing ultrasonic signals: by "primary" discrimination, and by "secondary" or "combinational" discrimination. Primary discrimination involves using only a single transducer to perform the study, while secondary or combinational discrimination utilizes multiple transducers and analyzes the combined signals from these transducers. The Gunkel patent further explains that

> insofar as is known, the prior art systems for defect discrimination have been primary discrimination systems which recorded the signals from the various transducers independently and relied upon analysis by the operator to provide the secondary information. However, such systems rely heavily upon the accuracy and judgment of the operator and provide considerable opportunity for human error.
>
> These disadvantages of the prior art systems are overcome with the present invention and novel means are provided for performing the secondary discrimination electrically in a manner which is substantially instantaneous and which completely eliminates the possibility of human error.
>
> The advantages of the present invention are preferably [**27] attained by providing novel means for ultrasonic inspection comprising a plurality of transducers, means for performing a primary discrimination of the signals from each of the transducers and electrical means for comparing and analyzing the results from all of the transducers to perform a secondary discrimination.

Although, as indicated, the district court noted that the Gunkel device used "multiple transducers [that] transmit[] ultrasonic signals as the pipe [is] rotated spirally past the patented device," apparently the court failed to recognize that a necessary element of the Gunkel device was the comparison of the data it obtained from the multiple transducers. In this respect, the Gunkel device performed a similar function to the correlation and combination functions of the *'006* patent.

The district court also erred in distinguishing the *'006* patent from the prior art on the ground that, unlike the prior art, "the patented device transverse[d] [sic] the internal bore of the material being inspected both axially and circumferentially and accomplish[ed] the inspection from the internal diameter of the item being inspected." Claims 1, 2, 7, 8, and 10, [**28] however, do not require longitudinal or circumferential movement of the probe. Only claim 3 requires such movement, and the Nimrod article clearly shows an angular drive means and a longitudinal drive means which operate independently of each other.

One of the differences between the claims of the *'006* patent and the Nimrod device was that the former, but not the latter, used multiple transducers. The district court found, however, and the finding is not challenged on appeal, that it was well known in the industry since 1960 that multiple transducers could be used simultaneously to scan an object. Additionally, the Gunkel patent indicates the utility of correlating and combining information from multiple modes, since it points out the disadvantages of using a single ultrasonic mode and the advantages of using multiple ultrasonic modes in a "secondary discrimination" system. Thus, standing alone, the prior art provides significant support for the appellants' contention that the *'006* patent would have been obvious.

3. [HN10] Prior art, however, cannot be evaluated in isolation, but must be [**29] considered [*1500] in the light of the secondary considerations bearing on obviousness. As we have pointed out:

> Evidence of secondary considerations may often be the most probative and cogent evidence of record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.

Stratoflex, 713 F.2d at 1538-39, 218 USPQ at 879; see also In re Piasecki, 745 F.2d 1468, 223 U.S.P.Q. (BNA) 785 (Fed. Cir. 1984).

In its lengthy discussion of secondary considerations, the district court found (a) that "the evidence is overwhelming that for well over a decade the industry had searched for a reliable method of detecting discontinuities in rotor forgings," (b) that "major turbine manufacturers had tried and failed to develop a reliable method of inspecting in-service turbine rotors," and (c) that "the patented device enjoyed commercial success and was perceived by Westinghouse and others as direct competition to Westinghouse's system of boresonic inspection." The appellants [**30] have not shown that those findings are clearly erroneous.

a. In 1963, ten years prior to the filing of the *'006* patent application, Westinghouse engineers were seeking a method of rotor inspection through the bore. A letter from one Westinghouse engineer to another said that "search units to examine rotors from the bore surface are and have been a need for many years" and that "there have been many times in the past when we could effectively use such units." At the time this letter was written, Westinghouse was using one of General Electric's boresonic test devices. Based on the letter, and testimony of Mr. Ronca and Mr. Renner of Westinghouse, the district court found that Westinghouse was not satisfied that the General Electric device was reliable.

The district court found that almost ten years later, in 1973, TVA asked Westinghouse to examine the possibility of performing rotor bore inspections. The district court based this finding on the testimony of Mr. Beck, a Westinghouse employee, that for a year following the Gallatin explosion, TVA insisted that Westinghouse obtain the capacity to perform rotor bore inspections.

b. The record shows that Westinghouse had attempted [**31] to discover a method of inspecting rotors from the bore, but had failed to find one that worked. Westinghouse department heads compared the device its own research and development efforts had produced, with Commercial's then existing device. Mr. Ronca's summary of the meeting states that some people present "expressed assessorial opinions regarding the technical superiority of the [Commercial] system. No attendee took exception to these assessments so acceptance of the [Commercial] system on a technical basis was considered unanimous." Later, Westinghouse had Commercial perform approximately 20 inspections for it using the device the *'006* patent covered, until Westinghouse had perfected its own system.

The evidence fully supports the district court's finding that others in the industry were unable to solve the problem. Westinghouse, a large corporation working on this matter, had tried but failed. Indeed, Westinghouse had pursued other solutions to the problem, using such technology as variable angle transducers, acoustical holography, and emersion testing. In 1972, when Commercial explained to Westinghouse officials its concept of a boresonic test apparatus, Mr. Ronca of Westinghouse [**32] stated that he thought the idea was not feasible because Westinghouse's own research endeavors to create such a device had failed. When shown in 1974 the Commercial device that the *'006* patent covered, Mr. Ronca expressed doubt that Commercial could have produced it. Yet two days later, Mr. Ronca wrote to Westinghouse department heads that "the [Commercial] system represents a significant advancement in the field of boresonics . . . ."

[*1501] c. The district court found, and the record shows, that Commercial had performed close to 100 inspections using the patented *'006* device, and that about twenty of those inspections had been performed for Westinghouse. The district court also cited a letter from Westinghouse to its field representatives urging them to discourage buyers from using Commercial's system and to push Westinghouse's system, from which the court inferred that Commercial was in active competition with Westinghouse in this technology. The court also cited a letter from an engineer at Detroit Edison stating that "[Commercial] is the forerunner and developer of on-site bore sonic [sic] and bottle bore equipment and are nationally recognized by EPRI [Electric [**33] Power Research Institute][,] Westinghouse, [General Electric] and others."

In this field of endeavor, where the number of bore inspections necessarily is relatively small, this is strong evidence of commercial success.

Westinghouse contends that these secondary considerations are irrelevant because Commercial's device did not operate effectively. Westinghouse cites the testimony of Dr. Gelhaus of EPRI describing Research Project RP502. In this project, Westinghouse and Commercial boresonic inspection devices were used to inspect a rotor that subsequently was cut apart and examined for defects. Dr. Gelhaus testified that the "techniques and the results were sorely wanting," and indicated that both test procedures produced inadequate results.

Batell Laboratories, one of the laboratories involved as an observer in the RP502 report, in reporting to the Consolidated Edison Company of New York on the analysis of stress and structural integrity it made of a generator rotor, stated that "the ultrasonic inspection of the rotor is by necessity performed from the bore surface only. Hence, flaw orientation is inherently difficult to determine. The system used by Commercial Machine Works [**34] represents the best solution available to this problem. Nevertheless, there is still a degree of uncertainty." Although Commercial's *'006* patented device might not have met Dr. Gelhaus' expectations, the industry apparently viewed the device as the best solution to the problem of boresonic inspection.

In light of the district court's findings and the evidence in the record, including the strong secondary considerations indicating nonobviousness, which weigh heavily in the determination of obviousness, *In re Piasecki, supra,* we agree with the district court's conclusion that the invention the *'006* patent covers would not have been obvious to one of ordinary skill in the art. This is one of those cases where evidence of secondary considerations "may . . . establish that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, 713 F.2d at 1538.*

IV

A. In finding that the Westinghouse device infringed the *'006* patent, the district court stated that Alco had presented "highly credible evidence, from two separate Westinghouse sources, that describe[d] Westinghouse's device for and method of boresonically inspecting [**35] turbine rotors," and that "neither defendant introduced evidence to discredit or rebut plaintiff's proof that the method and apparatus described in [the two sources] were the same method and apparatus used by Westinghouse to ultrasonically inspect TVA's rotors." The two Westinghouse sources were a Westinghouse Manual (called the "Blue Book") and a letter from Westinghouse's Steam Turbine Division Service Sales to one of its sales representatives that described the Westinghouse boresonic inspection system. The district court also noted that in an interrogatory Westinghouse had stated that it had used a boresonic system similar to the system described in the Blue Book to perform the TVA inspections.

The district court rejected the contention that Westinghouse's use of a gating procedure [*1502] avoided infringement. The court stated that gating is a means of masking unwanted data from the recorder so that only the relevant portion of the collected data is displayed. The court found that Westinghouse inspected rotors using two separate scans in which one scan performed a shallow analysis by gating out the inner wall of the rotor and the portion of the rotor beyond about eight [**36] inches, and in which the other scan performed a deep analysis by gating out the inner wall, the outer wall, and that portion of the rotor within about eight inches from the probe. The district court found that the *'006* patent did not require the inspection to be made on a single pass and that the Westinghouse method examined the entire rotor.

Finally, the district court rejected the contention that Westinghouse's device did not correlate or combine its data. Based upon its examination of the evidence, the court found that the Westinghouse device correlated and combined the information from its boresonic inspection.

The court stated that, "based on the evidence presented, the Court finds plaintiff . . . has met its burden of proving infringement . . . [and that] . . . the accused Westinghouse device contains every element found in claims 1, 2, 3, 7, 8 and 10 of the *006* patent."

B. In their appeal the appellants challenge, on various grounds, the finding that the Westinghouse device correlates or combines the data it obtains from the boresonic inspection of the rotor. As in the case of the appellants' challenge to the factual determinations underlying the conclusion of nonobviousness, [**37] our review of the record satisfies us that the findings relating to infringement are not clearly erroneous and were based upon correct legal standards.

1. The appellants first contend that there is no evidence that Westinghouse correlates or combines transmitted data using unreflected signals, as the *'006* patent requires. This argument rests upon a misconstruction of the patent claims. All of the claims specifically state that the correlation of the "information content" of the reflected and unreflected (transmitted) signals is accomplished "by precisely locating in a three-dimensional matrix the path through the rotor mass of each transmitted ultrasonic signal and the position of discontinuities in the rotor material evidenced by each reflected ultrasonic signal . . . ." If there is no reflected signal, the information content is that there is no indication of a flaw when viewed from that ultrasonic mode at that angle. The district court correctly

interpreted the claim language and applied it to Westinghouse's device.

2. The appellants next contend that the Westinghouse device uses a two-mode inspection only in the area from 3 to 8 inches from the bore and therefore does not [**38] operate "throughout the mass of the rotor material" as the patent claims require. Again, the appellants misread the claims.

The phrase in the claims, "the information content of said transmitted and said reflected signals relating to discontinuity characteristics throughout the mass of the rotor material," is a dependent clause which explains the meaning of the term "information content" used earlier in the claim. It requires not that the entire rotor be inspected with two modes, but only that the entire rotor must be inspected and the data correlated. Had the Westinghouse device inspected only a volume from three to eight inches from the bore with two ultrasonic modes, it would have avoided literal infringement. The Blue Book, however, states that "echos from about just beneath the bore surface to just beneath the exterior surface are recorded." Westinghouse searches the entire mass of the rotor and, therefore, literally employs this element of the *'006* patent.

3. The appellants argue that the Blue Book and the interrogatory answer do not prove that the Westinghouse device correlates and combines its data. This argument, however, ignores the third item of evidence upon which [**39] the district court relied, the letter from Westinghouse to one of its sales representatives. That letter describes the correlating and combining aspects of the Westinghouse device in terms [*1503] almost identical to the claim language: "a plot can be made which gives a spacial [sic] representation of the [defect's] size, shape, orientation and location."

4. Finally, the appellants contend that the district court inferred the existence in the Westinghouse device of an apparatus or means to correlate and combine data. With respect to the correlating feature, the Blue Book states that "the amplitude and length of time required for an echo to return is recorded, along with the longitudinal position and the rotational orientation. . . . Thus, the recorded echo time, longitudinal position and rotational position permit an accurate location of any discontinuity." Elsewhere the Blue Book states that

> each scan group is made with three ultrasonic transducers scanning simultaneously. Each transducer has a different orientation relative to the rotor interior. This not only permits a cross check of any ultrasonic findings by a single transducer but also permits the analyst [**40] to more precisely determine the location and orientation of any cracks or flaws that exist within the rotor interior.

As the district court found, since the Westinghouse device correlates the data, it must also have a means for doing so.

With respect to the combining aspect of the Westinghouse device, we have already noted the language in the letter from Westinghouse to one of its sales representatives which, as the district court said, "is an echo of the *006* patent's claims."

5. [HN11] Although the evidence of infringement is circumstantial, that does not make it any less credible or persuasive. *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 U.S.P.Q. (BNA) 805 (Fed. Cir. 1986).* In view of the nature of the device and the function it performed, it is not surprising that Alco was unable to produce direct evidence of infringement. Alco hardly could have been expected to present eyewitnesses to the use and operation of the Westinghouse device who would compare the Westinghouse device to the *'006* patent claims. The evidence Alco produced, however, is [**41] adequate to support the district court's finding that the Westinghouse device infringed the claims of the *'006* patent.

CONCLUSION

The judgment of the district court that the claims of the *'006* patent are valid and enforceable and that Westinghouse infringed those claims is affirmed.

AFFIRMED.

CONCURBY:

NIES

CONCUR:

NIES, Circuit Judge, concurring.

I concur in affirming the judgment of the trial court. In my view, appellants have failed to carry the burden of showing reversible error.

On the issue of infringement, appellants argue that the district court erred in holding that the Westinghouse "device" possesses a *means* to correlate and combine. Alco correctly asserts that claims 1, 2, and 3 require no such means. Those claims cover a device which produces data which is capable of being correlated and combined. Westinghouse's equipment also produces such data.

Thus, the district court's holding -- which was made, in any event, only with respect to claim 3 -- is harmless error. With respect to claims 7, 8, and 10, the method claims, those claims do include a step of correlating and combining the data. Westinghouse conceded that it does on occasion *itself* correlate or [**42] combine information, not merely furnish the data to others. Thus, that limitation in the method claims is met. I agree with Judge Friedman's infringement analysis in other respects and agree that all claims were proved to be infringed.

I also concur with Judge Friedman that the district court's conclusion that the claims are not invalid under section 103 cannot be disturbed. I believe, however, Judge Friedman misreads the district court's differentiation of the subject claims over the prior art Gunkel patent. Precisely, the district court spoke of no prior art teaching the correlation of *reflected* and *unreflected* signals. That Gunkel combined signals from multiple transducers [*1504] does not contradict the district court. Thus, I do not agree that the district court "failed to recognize" that Gunkel taught combining signals. Gunkel is irrelevant to the point the court was making. Indeed, I believe much labor is expended unnecessarily to uphold the patent on the record before us. Given the unique problems of on-site inspection of huge turbine rotors, Westinghouse's argument that the claims would have been obvious from the teachings of various prior art references appears [**43] to me to be a classic case of hindsight selection. Moreover, the reaction of Westinghouse personnel to the demonstration of Alco's device is persuasive as indicia of nonobviousness.

The dissent rejects the evidence of commercial success on the ground that the success must be attributed to Alco's services, not to the invention. The dissent considers that the examiner erroneously allowed amendments to the claims with respect to combining and correlating data which have no support in the specification. I disagree. Although raised below, there is no section 112 issue on appeal directed to the adequacy of the disclosure to support the claim language with respect to correlating and combining data. Such an assertion of error would be meritless. A fair reading of the specification supports the language of the claims, including the specific step in the method. The whole purpose of the acquisition of the data is to put the data together in a meaningful way so that the location and nature of flaws can be determined. The actual techniques for correlation and combining data are admitted by the parties to be well known in the prior art and are, thus, not required to be described in the specification. [**44] Thus, I depart from the dissent's analysis of this issue as a predicate for the denigration of the evidence of commercial success.

One final point, the panel has considered the question of this court's jurisdiction over the appeal, which depends upon the jurisdiction of the district court being based on *28 U.S.C. § 1338*(a). That section, in turn, requires that the claim arise under "an Act of Congress relating to patents." This suit is based on *16 U.S.C. § 831r* which is part of an Act "to improve the navigability and to provide for the flood control of the Tennessee River" and similar purposes. Judges Friedman and Rich conclude that the claim arises under an Act relating to patents; I do not. In my view a *16 U.S.C. § 831r* claim against TVA is more comparable to a claim under *28 U.S.C. § 1498* (1982) for reasonable compensation for use of a patented invention by the government, which does not arise under a patent statute, *Motorola, Inc. v. United States, 729 F.2d 765, 768, 221 U.S.P.Q. (BNA) 297, 299 (Fed. Cir. 1984),* and cases cited therein, than to a claim for patent [**45] infringement under *35 U.S.C. § 271.* The only decision directly bearing on this question was rendered in this very case by Judge Brown (reported at *448 F. Supp. 1175 (1978)).* In dismissing a claim against Westinghouse, Judge Brown held that Westinghouse could not be an infringer in view of the right of TVA to use the patented invention. Thus, this is a suit for compensation for a *lawful* use, not a suit for *unlawful,* i.e., infringing, use. That the word "infringed" as well as "used" appears in *16 U.S.C. § 831r* does not mean that Alco's claim is necessarily for patent infringement or arises under an act relating to patents.

DISSENTBY:

RICH

DISSENT:

RICH, Circuit Judge, dissenting.

The decision below is reported at *597 F. Supp. 133, 224 U.S.P.Q. (BNA) 577 (1984).* Reference will be made to the opinion as there published.

I am constrained to dissent from the majority's holding that the six claims in suit are not invalid for obviousness in view of the prior art under *35 USC 103.*

The majority opinion, after obviously careful consideration of the facts, preliminarily arrives at the conclusion [**46] that the claims in suit define only obvious subject matter and then reverses that conclusion because of the "secondary considerations," which I shall discuss further, concluding that

> [*1505] This is one of those cases where the evidence of secondary considerations "may . . . establish that an invention

> appearing to have been obvious in light of the prior art is not." *Stratoflex, 713 F.2d at 1538 [218 USPQ 871, 879 (Fed. Cir. 1983)].*

This is my point of disagreement. This is *not* one of these cases because, also per *Stratoflex*, a nexus is required between the invention disclosed in plaintiff's *patent* and the secondary considerations. No such nexus exists here.

The majority, like the trial judge, has been led astray and has assumed that the patent in suit is on some imaginary "system" for detecting flaws, which has enjoyed commercial success in the hands of Alco and was copied by Westinghouse, thus changing the prima facie obvious invention into a patentable invention.

What has happened here is that by a kind of magician's distracting patter, the purpose of which is to keep the viewer from observing what is actually happening, [**47] attention has been directed to the patent's claims to the exclusion of its *disclosure*. As the prosecution history shows, by a series of amendments the claims acquired a kind of life of their own, *divorced from the disclosure* of the patent's specification, including reference to what the majority opinion identifies as the "center" around which the contentions of the parties on appeal now revolve, namely, "the language of the claims that pertains to *combining* and *correlating* the information derived from the ultrasonic scans." (My emphasis.)

The sole function of claims is to delineate the *scope of protection* afforded by the patent, not to *describe* what the patentee has invented. Claim language, by law, is supposed to find support in the specification. Unsupported claim limitations should be ignored in appraising commercial success, though it could be a ground for invalidating the claim, but I am not discussing that issue. In determining what was invented, the specification must be considered in the state in which it was filed and the *original* claims, which are a part of it, may be regarded as a part of that disclosure. The patent and its file history, which [**48] are legal documents, are before us and it is necessary to consider them to determine what the invention disclosed therein truly is. In fact, that should be the first order of business. The salient fact that emerges from such examination is that *there is no reference whatsoever in the specification and original claims, taken together, of combining or correlating anything*, or of any means for or method of performing the function of combining or correlating. These are simply *terms* injected into the claims by the prosecuting attorney, without any support in the disclosure, in an effort to persuade the examiner that the claims patentably *distinguished* from the prior art he had cited against them. It does not appear to me that the examiner ever compared the claims he allowed with the disclosure to see if they are supported by it.

When the majority opinion refers to "the meaning of combining and correlating used in the patent" (in Part III, A) it must be borne in mind that those terms are not "used in the patent" insofar as the *disclosure* thereof is concerned, but merely appeared in the claims long after the application was filed. It must also be borne in mind that the majority [**49] has correctly held that "one skilled in the art would have known [before Smith's invention] how to combine and correlate the ultrasonic scan data" -- a finding also made by the trial court -- for which reason it is part of the prior art and therefore *can be no part of what Smith invented.* It was a skill of the art and a difficult one at that, comparable to the skill required of a radiologist in interpreting X-rays or CAT scans in deducing the existence of tumors.

Prima Facie Obviousness

The majority finds significant error by the district court in the following respects:

1. In failing to realize that the Gunkel patent reference, not considered by the PTO, discloses electrically *combining* ultrasonic [*1506] signals from multiple transducers, in a flaw detection system, to compare and analyze the results, and thus "performed a similar function to the combination and correlation functions of the *'006* patent [claims]." (Of course, as I have just pointed out, the *'006* patent in suit *does not disclose* any such functions.)

2. In not understanding that the "Nimrod" article reference (Brooks et al. "Ultrasonic Inspection of the Nimrod Power Plant Alternator [**50] Rotors") discloses both longitudinal and angular drive means for the ultrasonic inspection of rotor bores. Those are the very same functions Smith's apparatus was designed to perform, in which, therefore, there is no novelty.

The majority also notes that the district court correctly found that it had been *well known in the industry since 1960* that multiple transducers could be used simultaneously to scan an object and that this finding is not challenged on appeal.

On the basis of the foregoing, the majority holds that "the prior art provides significant support for appellants' contention that the *'006 patent* would have been obvious," (my emphasis) by which, I presume, the majority means that the *inventions* (apparatus and method) of the claims in suit would have been obvious. This is what I refer to as its holding of prima facie obviousness, with which I wholeheartedly agree. As a preliminary to discussing why the majority should not back away from that holding, let me summarize in one

paragraph what the basis of that finding of prima facie obviousness is.

Long prior to Smith's supposed invention, the ultrasonic detection of flaws in metal parts was a highly developed [**51] and sophisticated art. Smith's filing date was Dec. 3, 1973. Over ten years before that, Gunkel taught the use of multiple transducers operating simultaneously, longitudinally of and around tubular articles such as pipe, but on the outside, to detect flaws with use of electrical analysis means *to combine and correlate* the data produced by the transducers and their related pickups, to detect and appraise the nature of flaws. Gunkel proposed using as many as four transducers generating as many different modes of signals to get as many different kinds of data. The Nimrod disclosure shows the use of ultrasonic testing conducted *from the inside of a bore* of a shaft, as in the *'006* patent, through which the transducers are moved longitudinally and angularly rotated. Necessarily, some indexing means for accurately determining where the transducers are at the time when any given signal is received must be, and was, employed in all such apparatus or it would not be known where the flaws are. So the patentee did not invent that function.

What the *'006* patent *discloses* as Smith's invention is simply a piece of mechanism for use in selectively positioning one or more transducers [**52] and pickups in a bore and simultaneously "indexing" to indicate or record the longitudinal and angular position, i.e., the exact location, of the transducers in the bore to show where they are when signals are received. *The totality of Smith's disclosure of what he does with any signals received* is contained in the underlined words in the following sentence, taken in conjunction with the single "schematic" (i.e., not a working) drawing in the patent, reproduced below:

> If the propagated [ultrasonic] waves contact a flaw, there is a reflection to the pick-up means at the appropriate source 45 or 47, and *an appropriate indication is sent back to a recording or display device 87.* [Col. 5, lines 65-68.]

[*1507] [SEE ILLUSTRATION IN ORIGINAL]

The "recording or display device 87" is not described further but merely indicated, as some alternative and *presumed known device of the prior art*, by the square at the lower left corner of the schematic figure containing the number 87. Furthermore, it will be seen in the drawing that box 87 is shown as connected to a line 13. Line 13 is described in the specification (col. 3, 11. 35-39) as an "air line" [**53] which carries pneumatic pressure into the device to actuate the legs 11 on supports 3 and 5, a function totally unrelated to recording or displaying signals. Signals presumably would be conducted by "electrical lines 77" (col. 5, 1. 34), not further described and not shown as connected to anything, since the signals are electrical. *In sum, the patent disclosure is wholly devoid of any means or method for the "correlation of the information content of a transmitted or reflected ultrasonic signal" or for "combining the individual content" of signals* (to quote *claim* language) *or of any teaching of how to accomplish either of those functions.* The claims in suit, therefore, were created out of the whole cloth by the imagination of the prosecuting attorney and based on knowledge of prior art or subsequent events, not on the teachings of the *'006* patent. One must be wary of such expressions, used in the majority opinion, as "the device the *'006* patent covered" and "the patented *'006* device." They fail to distinguish between the *invention* disclosed in the patent and other things which may fall within the scope of the later-filed claims.

The majority opinion, at slip op [**54] page 9, refers to "an amendment" as containing the *inventor's* best description of "combining." What is in fact referred to is *attorney argument*, in connection with an amendment, during prosecution and contained in "AMENDMENT 'B'" in the section headed "REMARKS" (Apx. 158, 166, 170). This is no part of the patent disclosure and cannot be relied on to supply deficiencies therein. Even if it had been an actual proposed amendment, it would not be part of the disclosure, any more than attorney argument in this court. Attention is further directed to the fact that "Amendment 'B'" was refused by the examiner and *never entered* (A-176) and was replaced by "Amendment 'C'" (A-195). In any event it is not the *inventor's* description.

It is also a significant fact that the inventor, Robert D. Smith, named in the patent issued to Alco, left the employ of Alco in [*1508] October 1973 before the application was filed on December 3, 1973. He testified on deposition that after it was filed he never had any knowledge of the prosecution or any contact with the attorneys (A-1518, 1541-42).

When we come to examine whether there was commercial success of Smith's *invention* we are, [**55] of course, concerned only with the success of what he both invented and disclosed. *If there was commercial success, that success does not count in appraising non-obviousness unless it can be attributed to what he both invented and disclosed.* In light of all of the foregoing, I am convinced, as a matter of law, that unless there is a clear *nexus* between the *disclosed* subject matter of the patent (not just the vagueness of later-conceived broadly

worded claims) and very significant secondary considerations the claims are invalid for obviousness.

No Nexus

Without nexus, of course, the invention that is disclosed in the patent does not enjoy the benefits of commercial success in appraising its nonobviousness. The district court discusses nonobviousness beginning at *596 F. Supp. at 147, 224 USPQ at 586,* in part B of its opinion. Under sub-heading 3, "Ordinary skill in the art." The court several times refers to the invention of the patent as a boresonic inspection "system," or the "patented system." But *no system is disclosed* in the patent; the court must, therefore, have had in its mind something in addition to what the *'006* patent discloses. In section [**56] 4(c), "Commercial success," it gets to a brief discussion of that subject (F. Supp. at 153, USPQ at 591). One will search in vain for any description of just *what* it was that enjoyed commercial success. The record makes clear, however, that the Commercial Machine Works (CMW) division of Alco, which is supposed to have had the commercial success, was operating a *service business* of testing turbine rotors in the field, moving to the site with its equipment and personnel. One such test may take as long as a week or ten days, hundreds or even thousands of readings being taken (A-1016). When it is over, the net result is a report (A-1470) from CMW to the owner of the rotor saying what it thinks of the soundness of the rotor, what if any probable flaws or "discontinuities" have been found, and a record of its tests, columns of numbers representing "A" scan data (A-1469), which can be used later for comparison with subsequent tests. Nobody will ever know whether the report is or is not accurate, or how accurate, unless the rotor is physically altered by machining (as by "bottle-boring") (A-1474) or cut to pieces as a check on the tests.

Now, the totality of the commercial success [**57] found by the district court was that Westinghouse, which is a manufacturer of turbines, as well as a field-testing competitor of CMW, employed CMW in a crisis situation to test some 20 rotors in the field because it thought CMW was, at the time, the most competent operator in the field, and that CMW may have made a total of "[close] to a hundred" such inspections altogether. The question is, what does this prove about commercial success of the invention disclosed in the Smith patent, which is a piece of apparatus for locating transducers and pick-ups in a rotor bore -- nothing more. Is that apparatus the principal reason CMW was hired to make tests? Hardly. CMW was hired because *it* was considered competent to make tests. The apparatus disclosed in the patent is but *part* of the equipment necessary to obtain "A" scan data; it does not produce that data by itself, it only positions the transducers. The transducer must be powered by frequency generators, not shown but known to the prior art. The frequency generators must produce different frequencies. Different transducers must be used to produce different "modes" of ultrasonic waves, also not explained in the patent but known [**58] to the art. When the transducers are energized and send back data through the pick-ups, that electrical data must be recorded by undisclosed instruments (except for box 87), also known to the prior art. And even after that is done, the thus-recorded [*1509] data must be interpreted by highly trained and skillful personnel in order to provide the information being sought. (Wallace A-1468 et seq.; Gelhaus A-1493 et seq.) Computers may be used which have to be properly programmed. And when all is said and done, there is no assurance that the deductions from the data are really true.

What it comes down to is that CMW's success in selling its testing services to rotor users depended on its customer's confidence in CMW's abilities as the best available testing service organization. Since the most important aspect of such confidence, as the majority has deduced from these adversary proceedings, was CMW's technical ability through its personnel to *correlate* and *combine* the information content of the ultrasonic signals (matters on which the patent gives no instructions whatsoever) to arrive, perhaps with the aid of a "fracture mechanic's analysis" (A-1472), at conclusions on [**59] the condition of the rotor tested. Therefore, it appears clearly to me that the only commercial success relied on here or below cannot be attributed to Smith's invention as disclosed in his patent but must have been due primarily to other factors. It follows that there has been no showing of nexus between Smith's prima facie obvious invention and the commercial success to take the invention out of the obviousness category.

I also emphasize that what has become the crux of this case as the supposed contribution of the patentee -- correlating and combining data obtained from ultrasonic tests -- has been thoroughly established by the record as a technical skill which existed in the *prior art* long before the patentee's invention. The mere presence of these correlating and combining limitations in the *claims* by reason of an attorney's effort to distinguish them from the disclosures of references is not a justification for treating them as part of Smith's invention as though they were his contribution to the art. True, they are a vital part of CMW's *services*, which have been successfully sold, but correlating and combining remains knowledge of the art free for all to practice. [**60] What is free to all cannot be attributed to the patentee.

I would therefore hold the claims in suit invalid for obviousness under § 103.

The issue of *nexus* is definitely before us on appeal. Appellants' main brief devotes 10 pages to arguing *lack of nexus*, 20% of appellants' entire argument. Nexus is of the utmost significance in reaching the correct result on the obviousness issue because, as I have said, it is the *only* basis used by Judge Friedman to escape from his preliminary conclusion that the prior art makes the claims in suit obvious, which conclusion is clearly right.

Appellee has chosen to *avoid* answering the arguments that nexus was not established by almost totally ignoring them. Literally, its brief contains only a single short sentence on the question. It reads (p. 36):

> It is hard to see how there was a lack of nexus when Westinghouse copied *the patented invention* and even arranged with CMW to conduct inspections for it on a subcontract basis by utilizing the apparatus and method *that it had patented*. [Emphasis mine.]

Now, it is "the patented invention" that I have been discussing and what I mean by it is the invention [**61] that Smith made and disclosed in his patent. What else could he have patented? I have tried to determine whether the so-called commercial success which led the lower court and Judge Friedman, and apparently Judge Nies also, to find commercial success and thus nonobviousness is properly *attributable* to what Smith disclosed as his invention so as possibly to tip the scales in favor of finding prima facie invalid claims valid. I am convinced it is not. CMW's business success is not shown to be success of the Smith invention.

Judge Nies is swayed in favor of nonobviousness by "the reaction of Westinghouse personnel to the demonstration of *Alco's device*." (My emphasis.) What device? The person from Westinghouse who was swayed was Gilbert E. Ronca. His [*1510] testimony is not voluminous (A-1070-1135) and it clearly shows what impressed him. It was definitely *not* the disclosure of Mr. Smith's patent. I will summarize what the record shows.

Mr. Ronca was sent by Westinghouse to CMW to look at their boresonic *system* (A 1106). There was nothing new about boresonic systems as such; General Electric had one and the Nimrod apparatus was another. Smith did not invent, and [**62] his patent does not disclose, a "system," yet that is what everyone involved in this case, including the trial court, persistently talks about. A system is, of course, what one has to have to do boresonic testing. Mr. Ronca saw a demonstration of the *CMW system*, not the invention, and he was given information about it by two employees of Southwest Research Institute, which had built the system for Alco (CMW). The Southwest people were longtime experts in ultrasonic testing, research, and equipment design. In fact they appear to have designed the device shown in Smith's patent. In fact, the schematic drawing of the patent appears to have been copied from a submission to CMW from Southwest. Mr. Ronca wrote a report and he testified about his impressions *of the CMW system*. He said, "The system is very flexible and is functionally modular. By using the building block concept, the number and the type of examinations can be suited to a pre-established examination program. . . . The equipment used had a.001 inch reset capability, both in the axial and circumferential directions." (A 1125) "As I tried to describe, the system was described as accepting preprogrammed P.C. [printed circuit] [**63] boards which offered a selection of scanning sequences such as scanning axially over a pre-selected length and indexing clockwise. . . . It had several different options. It also had options to accept different scan modes and different scan -- in a menu of scan programs, such as surface waves, any combination of shear waves and so forth. And these could be plugged into the system." (A 1127) Explaining the reference to "menu," Ronca said that there were also representations about the capability of "marrying" the CMW device to a mini-computer. Asked about that, he said "this was the reference I made on having a menu of protocols that could be inserted for scan purposes." (A 1130) On all of this, Mr. Ronca reported enthusiastically and recommended Westinghouse try to buy it.

One will search in the patent in suit in vain for any disclosure or teaching of the things that so impressed Mr. Ronca in the CMW *system* or for a disclosure of any system at all.

I reiterate that the only commercial success of the *CMW system* relied on below is that company's *testing* of a total of, perhaps, 100 rotors. That testing was necessarily done by using the system, not merely the device shown [**64] in the patent, which in itself cannot test anything. There is no showing that the tests were accurate and there is considerable evidence that they may not have been. *All we know is that CMW was hired to do them* because their customers considered them competent. To my mind, that is no proof that CMW's success in getting that much testing business was due to the invention disclosed in Smith's patent. All it can do is position transducers in a bore and tell you where they are. That had been done in the prior art. One always has to know where the transducers are or it is impossible to determine where the flaws, if any, are. The accuracy with which it does so depends entirely on the refinement of the machining by which the locator is manufactured. The Nimrod boresonic device was said to be just as accurate, if not more so. All the rest -- the interpretation of the signals to acquire some intelligence and the apparatus and instrumentation essential thereto -- was the *common*

knowledge of the ultrasonic nondestructive testing art, as my colleagues point out whenever I suggest non-disclosure of some claim limitation in the patent.

One should not be overly impressed by the background [**65] recitation of nonspecific, arcane, ultrasonic terminology about wave propagation modes, all of which was knowledge in the public domain. Aside from Smith's piece of machinery, which is generally [*1511] described without particularization on the basis of a mere schematic figure, Smith does not give a single example of how to practice any method. He merely recites a multitude of general possibilities. Neither does he explain how to achieve his much-touted thousandth of an inch location accuracy.

I hesitate to suggest that my learned colleagues have been gullible, but on the subject of "commercial success" it does seem to me that they have been unduly moved by mere words and innuendos. Just what was the supposedly successful *CMW system*? They do not say. I have seen no reference in the briefs to any clear evidence on the subject and have been unable to find it in the voluminous record.

It is asserted as another indicium of nonobviousness that Westinghouse "copied" *the CMW system* and used it to do testing for TVA. There is a picture of the transducer-carrying head used by Westinghouse at A 536.20 and at tab 7 of appellants' brief. It bears little resemblance to the schematic [**66] drawing of Smith's patent. Where, then, do we find the evidence of the commercial use *of the invention disclosed in the patent* in either the CMW system or Westinghouse's alleged infringing copy? Unless and until it has been shown that there has been commercial use of the piece of mechanism disclosed in Smith's patent (which is not a system) there has been no proof of commercial success of his invention and no evidence establishing the necessary *nexus*. Finding no nexus, I would hold the claims in suit obvious and invalid under *35 USC 103*.

Jurisdiction

I join Judge Friedman in finding that this court has jurisdiction and find no merit in Judge Nies's grounds for questioning it. Notwithstanding the location of § 831r in a title of the U.S. Code other than Title 35, the section is an Act of Congress relating to patents, as is *28 USC 1498* which is controlling on other suits against the government for the use of patented inventions. *Motorola, Inc. v. United States, 729 F.2d 765, 221 U.S.P.Q. (BNA) 297 (Fed. Cir. 1984)* says nothing to the contrary.

Having given consideration to *16 USC § 831r* [**67] for the first time in connection with this appeal, I am impelled to say that it is, from the standpoint of patent law, one of the most ineptly drafted statutes I have seen, displaying a confusion between patents and patented inventions, and a total lack of comprehension of what the patent right is. One cannot copy a patent right, which is only the right to exclude, or use it, or employ it, all of which § 831r mentions in meaningless confusion. Only the owner of a patent or an exclusive licensee with the right to sue, who is a virtual owner, can use or employ the right to exclude. In spite of these misfortunes, however, the intent is clear that when TVA uses a patented invention and thus infringes the patent, the exclusive remedy is a suit against TVA "on the equity side of the appropriate district court of the United States. . . ." Since this is an act relating to patents, jurisdiction of the district court is under *28 USC § 1338*(a) and we have jurisdiction under *28 USC § 1295*(a)(1).

LEXSEE

SCRIPPS CLINIC & RESEARCH FOUNDATION, REVLON, INC., and RORER GROUP INC., Plaintiffs-Appellants, v. GENENTECH, INC., Defendant/Cross-Appellant, and MILES, INC., Defendant-Appellee. SCRIPPS CLINIC & RESEARCH FOUNDATION and REVLON, INC., Plaintiffs-Appellants, v. CHIRON CORPORATION, Defendant-Appellee

Nos. 89-1541, 89-1542, 89-1543, 89-1646, 89-1647

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

927 F.2d 1565; 1991 U.S. App. LEXIS 3925; 18 U.S.P.Q.2D (BNA) 1001

March 11, 1991, Decided

SUBSEQUENT HISTORY:

As Corrected March 26, 1991. Rehearing Denied April 30, 1991, Reported at: *1991 U.S. App. LEXIS 8701.* Suggestion for Rehearing In Banc Declined May 14, 1991, Reported at: *1991 U.S. App. LEXIS 33486.*

PRIOR HISTORY: [**1] Appealed from: U.S. District Court for the Northern District of California; Judge Schwarzer.

DISPOSITION:

Affirmed In Part, Reversed In Part, Vacated In Part, And Remanded

CASE SUMMARY:

PROCEDURAL POSTURE: Consolidated appeals from the United States District Court for the Northern District of California, which issued four opinions concerning litigation about a patent for a complex protein essential to blood clotting and decided several motions for summary judgment. Each party challenged the adverse decisions against that party.

OVERVIEW: Plaintiffs, assignee and licensees of a patent for a complex protein naturally occurring in normal blood and essential to blood clotting, sued defendants for patent infringement. In four opinions, the district court decided several motions for summary judgment. By appeal and cross-appeal, each party challenged the adverse decisions against that party. The court held that the element of intent was essential to the defense of inequitable conduct, and remanded the dispute about the credibility of the inventors' statements about the purity of the product. Subjective intent was not determinative of the need for a reissue application, however, and so plaintiffs were entitled to summary judgment on that issue. Defendants' contention that the reverse doctrine of equivalents applied raised questions of scientific and evidentiary fact requiring a trial. The court also held that product-by-process claims were not limited to product prepared by the process set forth in the claims.

OUTCOME: The court decided the issues were appropriately decided summarily, including plaintiffs' need for a reissue application and compliance with the best mode requirement. The court reversed and remanded the issues on which summary judgment was inappropriately granted, including the defenses of inequitable conduct, enablement, and anticipation.

LexisNexis (TM) HEADNOTES - Core Concepts:

Civil Procedure > Summary Judgment > Summary Judgment Standard

[HN1] Summary judgment is a useful procedural tool whereby an unnecessary trial is avoided when there are no material facts in dispute. However, summary proceedings are not intended to substitute for trial when it is indeed necessary to find material facts. A factual question is material if a reasonable jury could return a

verdict for the non-moving party based at least in part on its determination of the factual question. In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the opponent of the motion, and doubts resolved in favor of the opponent.

Civil Procedure > Summary Judgment > Burdens of Production & Proof

[HN2] A motion for summary judgment must be supported with a sufficient showing to establish that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. The burden of establishing entitlement to summary disposition is with the movant, with due consideration to the burden of proof. When a sufficiently supported motion has been submitted, the burden of coming forward and showing that there is a genuine issue of material fact shifts to the non-movant. All that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial. However, if the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.

Patent Law > Specification & Claims > Enablement Requirement

[HN3] The enablement requirement set forth in *35 U.S.C.S. § 112,* para. 1, is that the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. The purpose of this provision is to assure that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and the knowledge in the art.

Patent Law > Specification & Claims > Enablement Requirement

[HN4] Open-ended claims are not inherently improper; as for all claims their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art. They may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit.

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect

[HN5] The materiality of a representation, and whether the representation was made with intent to deceive or mislead, are the two essential factual predicates to determination of inequitable conduct. The element of intent is essential as a matter of law to a ruling of inequitable conduct. Conduct that requires forfeiture of all patent rights must be deliberate, and proved by clear and convincing evidence.

Civil Procedure > Summary Judgment > Summary Judgment Standard

[HN6] The fact that both sides moved for summary judgment does not establish that there is no issue of fact and require that judgment be granted for one side or the other.

Civil Procedure > Summary Judgment > Summary Judgment Standard

[HN7] Where there is a question of law, and the facts material to that question are not in dispute, the matter may be decided summarily.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN8] The reissue statute, *35 U.S.C.S. § 251,* provides in part that whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application. No new matter shall be introduced into the application for reissue.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN9] The applicant for reissue must specify the errors relied upon, and how they arose or occurred, and must distinctly specify the excess or insufficiency in the claims; and the applicant must declare the absence of deceptive intention.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN10] Under *35 U.S.C.S. § 251,* broadened claims by reissue must be applied for within two years of grant of the original patent.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN11] An error of law is not excluded from the class of error subject to correction in accordance with the reissue statute. Although attorney error is not an open invitation

to reissue in every case in which it may appear, the purpose of the reissue statute is to avoid forfeiture of substantive rights due to error made without intent to deceive. The reissue statute is based on fundamental principles of equity and fairness. When the statutory requirements are met, reissuance of the patent is not discretionary with the Commissioner; it is mandatory.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN12] The law does not require that no competent attorney or alert inventor could have avoided the error sought to be corrected by reissue. Failure of the attorney to claim the invention sufficiently broadly is one of the most common sources of defects in patents. The fact that the error could have been discovered at the time of prosecution with a more thorough patentability search or with improved communication between the inventors and the attorney does not, by itself, preclude a patent owner from correcting defects through reissue.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Reissue

[HN13] Subjective intent is not determinative of whether the applicants erred in claiming less than they had a right to claim. Intent to claim is not the criterion for reissue, and has been well described as but judicial shorthand, signifying a means of measuring whether the statutorily required error is present. The statutory standard of reissuable error is objective, and does not require proof of subjective state of mind. Determining what protection an inventor intended to secure by an original patent for the purposes of *35 U.S.C.S. § 251* is an essentially factual inquiry confined to the objective intent manifested by the original patent.

Civil Procedure > Summary Judgment > Summary Judgment StandardPatent Law > Novelty & Anticipation

[HN14] The patent law issue of anticipation is a question of fact. To make such finding on summary judgment, the court must determine that no facts material to the question are disputed; or that even if all material factual inferences are drawn in favor of the non-movant, there is no reasonable basis on which the non-movant can prevail. The standard of proof that would have to be met at trial must be considered.

Patent Law > Novelty & Anticipation

[HN15] Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.

Patent Law > Novelty & Anticipation

[HN16] The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference.

Patent Law > Infringement > Acts of Infringement

[HN17] In patent cases, questions by affidavit is disfavored. Trial by document is an inadequate substitute for trial with witnesses, who are subject to examination and cross-examination in the presence of the decision-maker.

Patent Law > Specification & Claims > Best Mode

[HN18] Title *35 U.S.C.S. § 112* provides in part that the specification shall set forth the best mode contemplated by the inventor of carrying out his invention.

Patent Law > Specification & Claims > Best Mode

[HN19] Compliance with the best mode requirement is a question of fact, and invalidity for failure of compliance requires proof by clear and convincing evidence that the inventor knew of and concealed a better mode of carrying out the invention than was set forth in the specification.

Patent Law > Infringement > Claim Interpretation

[HN20] Claim interpretation is a question of law, having factual underpinnings. When the meaning of key terms of claims is disputed extrinsic evidence may be adduced including testimony of witnesses, and reference may be had to the specification, the prosecution history, prior art, and other claims.

Patent Law > Infringement > Doctrine of EquivalentsPatent Law > Infringement > Reverse Doctrine of Equivalents

[HN21] The so-called "reverse doctrine of equivalents" is an equitable doctrine invoked in applying properly construed claims to an accused device. Just as the purpose of the "doctrine of equivalents" is to prevent pirating of the patentee's invention, so the purpose of the "reverse" doctrine is to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention.

Patent Law > Infringement > Reverse Doctrine of Equivalents

[HN22] The reverse doctrine of equivalents flows from the Supreme Court's statement in Graver Tank that an accused article may avoid infringement, even if it is within the literal words of the claim, if it is so far changed in principle from a patented article that it performs the same or a similar function in a substantially

different way. Application of the doctrine requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims, which in turn is determined in light of the specification, the prosecution history, and the prior art.

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect
[HN23] A reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct.

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect
[HN24] When a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it can not be deemed to have been withheld from the examiner.

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect
[HN25] A reference that is material only to withdrawn claims can not be the basis of a holding of inequitable conduct.

Patent Law > Inequitable Conduct > Burdens of Proof
[HN26] The party with the burden of proof of inequitable conduct must meet the clear and convincing standard.

Civil Procedure > Appeals > Reviewability > Preservation for Review
[HN27] In the Ninth Circuit, an appeal from a final judgment may include challenges to all rulings that produced the judgment.

Patent Law > Specification & Claims > Claim LanguagePatent Law > Infringement > Doctrine of Equivalents
[HN28] Product-by-process claims are not limited to the product prepared by the process set forth in the claims.

COUNSEL:

William S. Feiler, Morgan & Finnegan, of New York, New York, argued for Plaintiffs-Appellants. With him on the brief were Eugene Moroz, Patricia S. Rocha, Bruce A. Pokra and Stephen V. Bomse, Heller, Ehrman, White & McAuliffe, of San Francisco, California, of Counsel.

James W. Geriak, Lyon & Lyon, of Los Angeles, California, argued for Defendant/Cross-Appellant. With him on the brief were Douglas E. Olson, Bradford J. Duft and Karol M. Pessin. Also on the brief were Thomas J. Morgan and Melvin Blecher, Lyon & Lyon, of Washington, District of Columbia, Arnold Sprung, Sprung Horn Kramer & Woods, of New York, New York, argued for Defendant-Appellee. With him on the brief were Nathaniel D. Kramer and Alan J. Grant.

William L. Anthony, Townsend & Townsend, of Palo Alton, California, represented Chiron Corporation. Of Counsel was Noemi C. Espinosa, Townsend & Townsend, of Palo Alton, California.

JUDGES:

Markey * and Newman, Circuit Judges, and Beer, District Judge. **

* Circuit Judge Markey vacated the position of Chief Judge on June 27, 1990.

** The Honorable Peter Beer, United States District Court for the Eastern District of Louisiana, sitting by designation. [**2]

OPINIONBY:

NEWMAN

OPINION:

[*1568] NEWMAN, Circuit Judge.

This litigation concerns a substance called human Factor VIII:C, a complex protein that occurs naturally in normal blood and is essential to the clotting of blood. The patent in suit, United States Reissue Patent No. *32,011* (the "R *'011*" patent), is entitled "Ultrapurification of Factor VIII Using Monoclonal Antibodies", inventors Theodore S. Zimmerman and Carol A. Fulcher. Assigned to Scripps Clinic and Research Foundation, it was licensed exclusively to Revlon, Inc. Subsequent to the filing of this suit Revlon sold its interest to Rorer Group, Inc.

By appeal and cross-appeal, the parties n1 raise various issues of patent validity and enforceability, infringement and inducement to infringe, and reissue law and practice, all of which were decided on motions for summary judgment. Each side challenges the decision of certain issues adverse to it, and the final judgment based thereon. n2

n1 The plaintiffs will be grouped as "Scripps" unless otherwise stated. The defendants will be grouped as "Genentech" unless otherwise stated.

n2 These consolidated appeals and cross-appeals arise from judgments and orders of the United States District Court for the Northern District of California. *Scripps Clinic & Research Foundation v. Genentech, Inc., 666 F. Supp. 1379, 3 U.S.P.Q.2d (BNA) 1481 (N.D. Cal. 1987); Scripps Clinic and Research Foundation v. Genentech, Inc., 678 F. Supp. 1429, 6 U.S.P.Q.2d (BNA) 1018 (N.D. Cal. 1988)* (on reconsideration); *Scripps Clinic and Research Foundation v. Genentech, Inc., 707 F. Supp. 1547, 11 U.S.P.Q.2d (BNA) 1187 (N.D. Cal. 1989);* and *Scripps Clinic and Research Foundation v. Genentech, Inc., 724 F. Supp. 690, 12 U.S.P.Q.2d (BNA) 1157 (N.D. Cal. 1989)* (Order).

[**3]

The Invention

Factor VIII:C, called the clotting or procoagulant factor, is found in all mammals, although it differs among species. It has been the subject of extensive scientific research, over many years. At the time the claimed invention was made, it was known that human Factor VIII:C is a complex protein produced by the Factor VIII:C gene and secreted into the blood stream. It occurs in normal blood plasma (plasma is the fluid fraction of blood) at a concentration of about 200 nanograms per milliliter. The total protein content of plasma is about 70 milligrams (0.070 gram) per milliliter; since a nanogram is one billionth of a gram, the total protein in plasma is 350,000 times greater than the Factor VIII:C protein in plasma. Most of the problems faced by researchers attempting to isolate Factor VIII:C were due to the amount and nature of the other proteins in the plasma.

It was known that in normal blood Factor VIII:C exists in complex association with another protein, named the "von Willebrand factor" or Factor VIII:RP (RP means "related protein"). The weight ratio of Factor VIII:C to Factor [**4] VIII:RP in normal blood is about 1:100.

Before the invention here at issue was made, scientists had succeeded in concentrating the Factor VIII:C in plasma. This concentrate has been used to replace transfusions of whole blood in the treatment of hemophilia. The process was expensive and, because of the large volume of whole [*1569] blood needed as starting material, the possibility of contamination and disease from impurities in the source blood, the large amount of extraneous plasma proteins in the concentrate, and the large volume of concentrate that still had to be administered to the patient, there has been a continuing search for improvement. The record reflects the difficulties, over decades of research, in isolating and studying Factor VIII:C. Scripps reports that Genentech's scientists had been working in the field and had not isolated human Factor VIII:C in sufficient purity and amount to conduct successful characterization experiments.

At the Scripps Clinic & Research Foundation, Dr. Zimmerman and Dr. Fulcher were studying Factor VIII:C from human and porcine blood. These scientists succeeded in isolating and, for the first time, characterizing Factor VIII:C, by a process of chromatographic [**5] absorption of the Factor VIII:C complex using monoclonal antibodies specific to Factor VIII:RP, followed by separation of the Factor VIII:C. n3 Monoclonal antibodies are produced by the cloned copies of a single hybridoma cell. A hybridoma is a hybrid cell that is immortal: that is, it does not die as do normal cells, but continues to reproduce clones that in turn produce a specific antibody. As described in the R *'011* patent, the hybridoma was made by fusing a mouse spleen cell that produced the desired antibody to Factor VIII:RP, with a mouse cancer cell, which contributed the immortality. The patent describes the method of assay for clones producing antibodies to VIII:RP, their isolation, and preparation of the monoclonal antibodies for use as the immunoadsorbent.

n3 Drs. Zimmerman and Fulcher characterized the Factor VIII:C using a technique described as SDS-gel ("SDS" stands for sodium dodecyl sulfate) electrophoresis and production of a precipitating heterologous antibody. This work was reported in Fulcher and Zimmerman, *Proc. Nat'l Acad. Sci. USA*, "Characterization of the Human Factor VIII Procoagulant Protein with a Heterologous Precipitating Antibody", Vol. 79, pp. 1648-52, March, 1982. It is not disputed that this is the first time that human Factor VIII:C was sufficiently pure to be characterized scientifically, and that the Zimmerman/Fulcher characterization is now the generally recognized "fingerprint" of Factor VIII:C.

[**6]

The claimed process whereby the Factor VIII:C/VIII:RP complex is separated from the other materials in blood, followed by separation of the VIII:C from the VIII:RP, is described in the R *'011* patent and was summarized by Scripps as follows:

> The first step involves the application of a solution containing Factor VIII complex

> (Factor VIII:C/Factor VIII:RP) to a column packed with agarose beads. Attached to the beads is a monoclonal antibody to Factor VIII:RP. The monoclonal antibody binds and immobilizes the Factor VIII:RP part of the Factor VIII complex while the non-Factor VIII materials simply pass through the column. A calcium salt solution is then applied to break the bond between the Factor VIII:C and the Factor VIII:RP. The Factor VIII:C is eluted from the column while the Factor VIII:RP remains bound to the antibody.

The procedure produces purified but dilute Factor VIII:C:

> After this first step the Factor VIII:C is highly purified, but dilute. A second step to concentrate the Factor VIII:C solution may then be performed. This involves absorbing the Factor VIII:C on an aminohexylagarose column. The Factor VIII:C on the aminohexyl column is then eluted with a very small [**7] amount of calcium salt solution, resulting in a highly concentrated solution of highly purified Factor VIII:C.

The potency and activity n4 of the fractions obtained by this technique were summarized by Scripps as follows:

> [*1570] When the Factor VIII:C is eluted from either type of column it is collected serially in a number of small, individual portions called "fractions." When the Factor VIII:C is eluted from the monoclonal antibody column, for example, the initial fractions will have little VIII:C. The VIII:C increases as the Factor VIII:C is released. After the majority of Factor VIII:C has been released, the later fractions will contain decreasing amounts.
> Table I in the Zimmerman patent contains an analysis of two individual fractions. Patent Fraction 3 has a potency of 1172 units/ml and a specific activity of 2294 units/mg. Patent Fraction 4 is from another experiment and has a potency of 545 units/ml and a specific activity of 2370 units/mg.

Issues raised in this litigation concern purified Factor VIII:C and the reliability and reproducibility of the process, as these aspects relate to the validity, enforceability, and infringement of the R *'011* patent claims.

> n4 "Potency" refers to the amount of activity in a given volume of solution. For example, if 1000 units of Factor VIII:C activity were dissolved in 1 milliliter (ml) of water, the potency of the solution would be 1000 units/ml.
>
> "Specific activity" refers to the number of units of activity for a given mass of protein. For example, if 1000 units of Factor VIII:C activity were present in 1/2 milligram (mg) of protein, the specific activity would be 2,000 units/mg.
>
> One "Unit" is defined as the activity present in 1 ml of normal plasma.

[**8]

The Claims

The claims in suit are product-by-process claims 13, 14, 17, 18, and 34, and product claims 24-29. Claim 13 is representative of the product-by-process claims:

13. Highly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1.

Claim 1 is:

> 1. An improved method of preparing Factor VIII procoagulant activity protein comprising the steps of
>
> (a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,
>
> (b) eluting the VIII:C,
>
> (c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,
>
> (d) eluting the adsorbed VIII:C, and
>
> (e) recovering highly purified and concentrated VIII:C.

Product claims 24-29 were added by reissue, and are the focus of most of the controversy:

> 24. A human VIII:C preparation having a potency in the range of 134 to 1172 units per ml, and being substantially free of VIII:RP.
> 25. A human VIII:C preparation of claim 24, wherein the VIII:C concentration is at least 160,000 fold purified relative to VIII:C in plasma. n5
> 26. A human VIII:C preparation of claim 24, [**9] wherein the ratio of VIII:C to VIII:RP is greater than 100,000 times the ratio in plasma.
> 27. A human VIII:C preparation of claim 24, wherein said VIII:C is isolated from VIII:C/VIII:RP and 90-100 percent of the VIII:RP has been removed.
> 28. A human VIII:C preparation having a specific activity greater than 2240 units/mg.
> 29. A human VIII:C preparation of claim 28 wherein the potency is in the range of 134 to 1172 units/ml.

> n5 "Fold purification" is the ratio of the specific activity of a protein sample to the specific activity of normal plasma. The Factor VIII:C specific activity of normal human plasma is known to be 0.014 units/mg. Thus the relationship is:
>
> fold purification = specific activity/0.014.
>
> For example, if a Factor VIII:C sample has a specific activity of 2240 units/mg, its fold purification value is 160,000. Stated another way, the sample is 160,000 times purer, as to Factor VIII:C, than normal plasma.

Summary Judgment

[HN1] Summary judgment is a useful procedural tool whereby an unnecessary trial [**10] is avoided when there are no material facts in dispute. However, summary proceedings are not intended to substitute for trial when it is indeed necessary to find material facts. *Meyers v. Brooks Shoe, Inc., 912 F.2d 1459, 1461, 16 U.S.P.Q.2d (BNA) 1055, 1056 (Fed. Cir. 1990)* ("the factual dispute should be reserved for trial"). A factual question is material if a reasonable jury could return a verdict for the non-moving party based at least in part on its determination of the [*1571] factual question. *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).* In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the opponent of the motion, *Poller v. Columbia Broadcasting System, Inc., 368 U.S. 464, 473, 7 L. Ed. 2d 458, 82 S. Ct. 486 (1961),* and doubts resolved in favor of the opponent. *Cantor, dba Selden Drugs Co. v. Detroit Edison Co., 428 U.S. 579, 582, 49 L. Ed. 2d 1141, 96 S. Ct. 3110 (1976).*

[HN2] A motion for summary judgment must be supported with a sufficient showing to establish that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett, 477 U.S. 317, 325, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986).* The [**11] burden of establishing entitlement to summary disposition is with the movant, with due consideration to the burden of proof. *Id.* When a sufficiently supported motion has been submitted, the burden of coming forward and showing that there is a genuine issue of material fact shifts to the non movant. The Court has observed that "all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Anderson, 477 U.S. at 249* (quoting *First National Bank of Arizona v. Cities Service Co., 391 U.S. 253, 288-289, 20 L. Ed. 2d 569, 88 S. Ct. 1575 (1968)).* However, "if the evidence is merely colorable, or is not significantly probative, summary judgment may be granted". *Anderson, 477 U.S. at 249-50* (citations omitted).

Scripps and Genentech both argue that certain issues that were decided summarily against each of them were not resolvable on summary judgment in favor of the other, if Rule 56 were correctly applied. We have concluded that the district court was correct in its determination, as to some of the issues in suit, that there were no questions of material fact; but not for all issues. [**12] For those issues that could indeed be decided summarily, we have reviewed the decision for correctness as a matter of law. For those issues on which summary judgment was inappropriately granted, we have reversed the grant and remanded for trial.

I

Inequitable Conduct and Enablement

On the basis of statements that the inventors made to the reissue examiner in connection with prosecution of the newly added product claims, issued as claims 24-29 of the R *'011* patent, the district court granted Genentech's motion for summary judgment of unenforceability of the claims based on inequitable conduct.

Although the court did not hold the claims invalid for lack of enablement, the issues of enablement and inequitable conduct were intertwined. [HN3] The "enablement" requirement is set forth in Title 35 as follows:

> *35 U.S.C. § 112* **para. 1**. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

The purpose of this provision is to assure [**13] that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and the knowledge in the art. *See United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 U.S.P.Q.2d (BNA) 1217, 1223 (Fed. Cir. 1988), cert. denied, 490 U.S. 1046, 109 S. Ct. 1954, 104 L. Ed. 2d 423 (1989).*

During prosecution of the reissue application the patent examiner had raised various questions under § 112, relating to the purity of the Factor VIII:C that was the subject of the proposed product claims. Communications from the inventors covered such matters as the presence of fibrinogen [*1572] and fibronectin and their removal by those skilled in the art; variations in chromatographic purification results; and the determination of purity using SDS-gels. The examiner requested a showing of the mathematical relationship between specific activity and fold purification, and other data, which the inventors provided.

The reissue examiner's objection to the scope of the product claims was withdrawn on the inventors' response that they had obtained human Factor VIII:C at "levels closely approaching the theoretical [**14] limit". The inventors explained that the difference in fold purification of about 169,000 shown in Table I, and their calculation of the theoretical value of 357,000-fold, was 2-fold, from which the inventors stated that the "specification teaches those skilled in the art the production of essentially pure VIII:C." They explained that the removal of any remaining fibrinogen and fibronectin was within the skill of the art, when these impurities were identified. The examiner, apparently satisfied with the inventors' answers, n6 granted the reissue application with the added product claims as amended.

> n6 The several defendants herein all presented arguments to the examiner, in Protests filed during the reissue proceeding, on why the product claims should not be allowed.

The inventors distinguished the case of *In re Fisher, 57 C.C.P.A. 1099, 427 F.2d 833, 166 U.S.P.Q. (BNA) 18 (CCPA 1970),* which held the open-ended claims there presented unpatentable for lack of enablement of "future compositions having potencies far in excess of those obtainable [**15] from his teachings plus ordinary skill". *Id.* at 839, 166 U.S.P.Q. at 24. [HN4] Open-ended claims are not inherently improper; as for all claims their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art. They may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit. *See Fisher, supra.*

While Genentech argues that the issue is whether the inventors misrepresented the purity of their Factor VIII:C, Scripps points out that the claims do not require 100% pure VIII:C. The product-by-process claims all refer to "highly purified and concentrated" VIII:C, and the product claims contain limitations that are met by less than 100% pure VIII:C: for example, that the VIII:C is "at least 160,000 fold purified relative to VIII:C in plasma" (claim 25), that "the ratio of VIII:C to VIII:RP is greater than 100,000 times the ratio in plasma" (claim 26), that the VIII:C product has a potency of 134-1172 units/ml (claim 24) or a specific activity of over 2400 units/mg (claim 28), and is substantially free of VIII:R (claims 24-27). Indeed, the district court [**16] did not find that all these claim limitations depended on the criticized representations about purity that were made to the examiner. However, the court found that the inventors' statements about the purity of the product were unsupported by evidence, and on this basis adjudged all the claims unenforceable for inequitable conduct.

The court referred to a Declaration by Drs. Zimmerman and Fulcher, during prosecution of the reissue application, that "we have achieved purified VIII:C at levels very near what we believe to be the theoretical values with the claimed process." The court found that "Drs. Zimmerman and Fulcher made crucial factual assertions, for the purpose of reversing the Examiner's initial rejection of the open-ended purity claims, for which they had no factual support." The court stated at the hearing that the inventors made statements about purity for which they did not have evidence:

> THE COURT: . . . and without implying improper motives it is an issue [purity] on which the inventors did not seem to have evidence but without evidence they created the -- well, you say they made a square statement saying that almost always will you get pure VIII:C when, in fact, they [**17] didn't know that you would almost always get pure VIII:C.

The district court expressed its concern about the inventors' knowledge of the reliability of the process:

> THE COURT: Mr. Feiler, I'm not questioning that they got pure C, they have [*1573] gotten lots of pure C. What they did not know was what is the probability of getting VIII:Cevery time you run one of these columns. What percentage of the fractions that come out will be pure VIII:C. They just didn't know.

This reasoning is reflected in the court's finding:

> The undisputed evidence shows that (1) only some of the fractions appeared to be free of fibronectin while others were not, (2) the inventors were unable to quantify how much fibronectin the stream of the product from the column contained, and (3) the fraction on which the patent application (Table I) was based contained up to 50% fibronectin.

Scripps, 707 F. Supp. at 1557, 11 U.S.P.Q.2d at 1196.

Scripps stated that the inventors' statements to the examiner were justified, that the inventors believed them to be correct, that there was evidence before the district court that the inventors obtained gels showing essentially pure Factor VIII:C, and that the inventors obtained [**18] immunological tests showing no evidence of fibronectin or fibrinogen. Scripps argued that the inventors had the good faith belief that they had enabled the preparation of pure Factor VIII:C, and referred to evidence of contemporaneous correspondence from Dr. Zimmerman to other scientists that "We believe that purification of the human VIII:C is essentially complete". There were declarations filed with the district court, of Dr. Katzmann (a scientist at the Mayo Clinic) and Dr. Hrinda (a scientist at Rorer), that the inventors had obtained essentially pure Factor VIII:C. Dr. Katzmann also explained that Factor VIII:C activity can vary in samples having the same degree of purity; Genentech's data showed the same effect. There was deposition testimony on tests by Dr. Fulcher, showing no fibronectin.

Genentech asserts that the inventors deliberately withheld an analysis of the Table I material after the examiner requested it, and misrepresented that the impurities were "trace" when in fact the materials described in the specification contained 50% fibrinogen and fibronectin. Scripps responds that the requested analysis of the Table I material was indeed provided, that the examiner understood and [**19] was not misled by the inventors' statements about purity, that additional evidence showed that the representations made to the examiner were scientifically correct, and that, in all events, the statements were made in good faith.

The district court placed substantial weight on Dr. Zimmerman's deposition testimony that "trace contaminants" fibrinogen and fibronectin remained, that he "did not have numbers for upper limits", and that "it is a trivial matter to remove the fibrinogen and fibronectin once they have been identified". The court commented that "Dr. Fulcher in her deposition was unable to quantify [the term 'essentially pure'] or the term 'highly purified'", and remarked that it is "impossible to extrapolate from one or several Laurells [tests of a fraction of the column stream] as to the degree of purity of the entire output". The court criticized these scientific facts as legal inadequacies.

The court appeared to require greater scientific precision than did any of the scientists whose testimony was presented. The statute, however, is directed to persons of skill in the field of the invention. Indeed, Genentech provided no evidence that one of skill in the field of this [**20] invention could not make and use a product satisfying all the limitations of the claims, by following the inventors' disclosure and the knowledge of the art. Neither evidence nor expert opinion to this effect was offered.

[HN5] The materiality of a representation, and whether the representation was made with intent to deceive or mislead, are the two essential factual predicates to determination of inequitable conduct. *Modine Mfg. Co. v. Allen Group, Inc., 917 F.2d 538, 541, 16 U.S.P.Q.2d (BNA) 1622, 1624 (Fed. Cir. 1990).* The district court stated that the "three elements of inequitable conduct" are "material prior information, chargeable to applicant, not disclosed to the PTO". *Scripps, 707 F. Supp. at 1557, 11 U.S.P.Q.2d at 1196.* Notably missing is the element of [*1574] intent, essential as a matter of law to a ruling of inequitable conduct. *See Kingsdown Medical Consultants, Ltd., v.*

Hollister, Inc., 863 F.2d 867, 876, 9 U.S.P.Q.2d (BNA) 1384, 1392 (Fed. Cir. 1988). Conduct that requires forfeiture of all patent rights must be deliberate, and proved by clear and convincing evidence. While Genentech argues that absence of reference by the court to intent does not mean that the court did not find intent, [**21] the court's remark that it was "without implying improper motives [to the inventors]" contravenes this argument. Even were the inventors' statements concerning purity in error, a finding of disputed fact that is not appropriate on summary judgment, the absence of a finding of intent to deceive or mislead the examiner precludes summary judgment of inequitable conduct. *See KangaROOS U.S.A., Inc. v. Caldor, Inc., 778 F.2d 1571, 1573, 228 U.S.P.Q. (BNA) 32, 35-36 (Fed. Cir. 1985)* (a disputed question of intent to deceive is not appropriate for summary resolution).

The grant of partial summary judgment of unenforceability of the R *'011* claims for inequitable conduct is reversed.

Scripps had filed a cross-motion for summary judgment on this issue. This does not, of itself, require adjudication in its favor. *United States v. Fred A. Arnold, Inc., 573 F.2d 605, 606 (9th Cir. 1978); accord, Cram v. Sun Insurance Office, Ltd., 375 F.2d 670, 673-74 (4th Cir. 1967)* ("The [HN6] fact that both sides moved for summary judgment does not establish that there is no issue of fact and require that judgment be granted for one side or the other"). These disputed factual questions of materiality and intent, which [**22] depend on the assessment of scientific facts as well as on the credibility of witnesses, are not amenable to summary resolution. The issue is remanded for trial.

II

35 U.S.C. § 251

A

The R *'011* patent is a reissue of Patent No. 4,361,509 ("the '509 patent"), granted on November 20, 1982. Genentech challenged the adequacy of the patentee's reason for seeking reissue, stating that this reason was insufficient in terms of *35 U.S.C. § 251.* On this ground the district court granted Genentech's motion for partial summary judgment of invalidity of claims 17, 18, 24-29, and 34.

Although there were factual aspects debated by the parties, they are not material to the question of the legal adequacy of the patentee's reason for requesting reissue. [HN7] That is a question of law, and the facts material to that question were not in dispute. The matter could have been, and was, decided summarily. *See Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys., 804 F.2d 659, 662, 231 U.S.P.Q. (BNA) 649, 651 (Fed. Cir. 1986), cert. denied, 480 U.S. 933, 94 L. Ed. 2d 764, 107 S. Ct. 1573 (1987)* ("These facts are not in dispute, though their legal significance is. Thus the basis on which the district court decided the question was amenable [**23] to summary judgment"). However, the district court erred in its conclusion of law.

[HN8] The reissue statute provides in part:

> ***35 U.S.C. § 251.*** Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall . . . reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application. . . . No new matter shall be introduced into the application for reissue.

In accordance with *37 C.F.R. § 1.175(a)(5)* and (a)(3) [HN9] the applicant for reissue must "specify[] the errors relied upon, and how they arose or occurred," and must "distinctly specify[] the excess or insufficiency in the claims"; and in accordance with *37 C.F.R. § 1.175(a)(6)* the applicant must declare the absence of deceptive intention.

The principal error that the inventors sought to cure was the claiming of "less than [they] had a right to claim in the patent" due to the omission of product claims. The '509 patent contained only process [*1575] and product-by-process [**24] claims. n7 In the reissue application inventors Zimmerman and Fulcher declared that they had always viewed the Factor VIII:C product as their invention, pointing out that the '509 specification stated that it was an object of their invention to produce highly purified Factor VIII:C.

> n7 [HN10] Broadened claims by reissue must be applied for within two years of grant of the original patent. *35 U.S.C. § 251.* This requirement was met.

----------End Footnotes---------- [HN11] -

An error of law is not excluded from the class of error subject to correction in accordance with the reissue statute. Although attorney error is not an open invitation to reissue in every case in which it may appear, *see In re Weiler, 790 F.2d 1576, 1579, 229 U.S.P.Q. (BNA) 673,*

675 (Fed. Cir. 1986) ("not every event or circumstance that might be labeled 'error' is correctable by reissue"), the purpose of the reissue statute is to avoid forfeiture of substantive rights due to error made without intent to deceive. *See generally Ball Corp. v. United States, 729 F.2d 1429, 1939 n.28,* [**25] *221 U.S.P.Q. (BNA) 289, 296 n.28 (Fed. Cir. 1984)* (the reissue statute "is based on fundamental principles of equity and fairness").

When the statutory requirements are met, reissuance of the patent is not discretionary with the Commissioner; it is mandatory ("shall"). *See In re Handel, 50 C.C.P.A. 918, 312 F.2d 943, 948, 136 U.S.P.Q. (BNA) 460, 464 (CCPA 1963)* ("the whole purpose of the statute, so far as claims are concerned, is to permit limitations to be added to claims that are too broad or to be taken from claims that are too narrow").

Genentech does not dispute that error was made, and does not challenge the principle of the availability of product claims to the purified Factor VIII:C. Further, Genentech does not assert that the attorneys' initial view of the unavailability of product claims involved any deceptive intention. The district court, holding that there was insufficient reason for reissue, appeared to interpret § 251 as requiring a showing that the error in claiming the product could not have been avoided, in order to be eligible for cure. This is not the framework of the reissue statute.

[HN12] The law does not require that no competent attorney or alert inventor could have avoided the error sought to be corrected by reissue. [**26] Failure of the attorney to claim the invention sufficiently broadly is "one of the most common sources of defects". *In re Wilder, 736 F.2d 1516, 222 U.S.P.Q. (BNA) 369 (Fed. Cir. 1984), cert. denied, 469 U.S. 1209, 84 L. Ed. 2d 323, 105 S. Ct. 1173 (1985):*

> An attorney's failure to appreciate the full scope of the invention is one of the most common sources of defects in patents. The fact that the error could have been discovered at the time of prosecution with a more thorough patentability search or with improved communication between the inventors and the attorney does not, by itself, preclude a patent owner from correcting defects through reissue.

Id. at 1519, 222 U.S.P.Q. at 371.

[HN13] Subjective intent is not determinative of whether the applicants erred in claiming less than they had a right to claim. *In re Mead, 581 F.2d 251, 255, 198 U.S.P.Q. (BNA) 412, 416 (CCPA 1978).* "Intent to claim" is not the criterion for reissue, and has been well described as "but judicial shorthand, signifying a means of measuring whether the statutorily required *error* is present." *In re Weiler, 790 F.2d 1576, 1581, 229 U.S.P.Q. (BNA) 673, 676 (Fed. Cir. 1986)* (emphasis in original). The statutory standard of reissuable error is objective, and [**27] does not require proof of subjective state of mind:

> Determining what protection [an inventor] intended to secure by [an] original patent for the purposes of § 251 is an essentially factual inquiry confined to the *objective* intent manifested by the original patent.

In re Rowand, 526 F.2d 558, 560, 187 U.S.P.Q. (BNA) 487, 489 (CCPA 1975) (emphasis in original).

On undisputed facts, the inventors established that they had claimed less than they had a right to claim, that they had [*1576] done so in error, and that there was not deceptive intention. The application for reissue fully complied with the statutory and regulatory requirements. n8

> n8 The patent examiner and the PTO Office of Quality Review found that the applicant adhered to correct reissue practice, pursuant to Manual of Patent Examining Procedure § 1456 (Rev. 3, 1986).

As a matter of law, reissue claims 17, 18, 24-29, and 34 are not invalid on this ground. The grant of partial summary judgment is reversed. On remand, partial summary judgment shall be entered for [**28] Scripps on this ground.

B

The district court had also held the reissue product claims invalid for inadequate support in the specification for their open-ended scope, referring to changes that Drs. Zimmerman and Fulcher made in the text of the specification during the drafting process. For example, they changed "virtually pure" to "highly purified"; and inserted "largely" before "free of contaminants". This is an issue of enablement, which is not challenged by Genentech; but it also raises questions of claim interpretation in light of the specification. In view of the several disputed questions of material fact underlying these issues, see Part I *ante* and Part V *post*, summary judgment on this ground was improper, and the grant thereof is reversed. This issue, also, requires trial.

III

Anticipation

The district court held, on cross-motions for summary judgment, that "it had been proved by clear and convincing evidence" that claims 24, 26, and 27 were invalid for anticipation, *35 U.S.C. § 102*(b), based on subject matter described in a 1979 dissertation by Robert B. Harris entitled "Isolation and Characterization of Low Molecular Weight, Non-Aggregated Antihemophilic Factor [**29] from Fresh Human Plasma".

A

[HN14] Anticipation is a question of fact. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 619, 225 U.S.P.Q. (BNA) 634, 637* (Fed. Cir.), *cert. dismissed, 474 U.S. 976, 88 L. Ed. 2d 326, 106 S. Ct. 340 (1985).* To make such finding on summary judgment, the court must determine that no facts material to the question are disputed; or that even if all material factual inferences are drawn in favor of the non-movant, there is no reasonable basis on which the non-movant can prevail. *Cooper v. Ford Motor Co., 748 F.2d 677, 679, 223 U.S.P.Q. (BNA) 1286, 1288 (Fed. Cir. 1984).* The standard of proof that would have to be met at trial must be considered. *Anderson, 477 U.S. at 257.*

[HN15] Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. *Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 138, 231 U.S.P.Q. (BNA) 644, 646 (Fed. Cir. 1986); RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 1444, 221 U.S.P.Q. (BNA) 385, 388 (Fed. Cir. 1984).* There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.

It is [**30] sometimes appropriate to consider extrinsic evidence to explain the disclosure of a reference. Such factual elaboration is necessarily of limited scope and probative value, for a finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. [HN16] The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference. *See Studiengesellschaft Kohle, mb H v. Dart Industries, Inc., 726 F.2d 724, 727, 220 U.S.P.Q. (BNA) 841, 842 (Fed. Cir. 1984)* (although additional references may serve to reveal what a reference would have meant to a person of ordinary skill, it is error to build "anticipation" on a combination [*1577] of these references). If it is necessary to reach beyond the boundaries of a single reference to provide missing disclosure of the claimed invention, the proper ground is not § 102 anticipation, but § 103 obviousness. Indeed, a publication on the Harris dissertation was included [**31] in the prior art statement filed by Scripps and was a cited reference under § 103.

B

In the summary judgment proceedings the parties filed three successive declarations of Dr. Harris, each explaining his dissertation. In the first declaration, filed by Miles, Inc., Harris stated that he isolated "a low molecular weight antihemophilic factor". In his second ("supplemental") declaration, filed by Scripps, Harris described this factor as not a naturally occurring substance, and of low specific activity:

> 6. The material I identified as low molecular weight antihemophilic factor (LMW-AHF) was not a naturally occurring substance. The material of my dissertation is the result of reacting plasma with a reducing agent called dithiothreitol (DTT) prior to purification. The reduced plasma is run through an initial purification step, and is then chemically reacted with radioactively labeled iodoacetamide (<14>C-IAA). This reduced and alkylated material was the LMW-AHF reported in my dissertation. After further purification, I obtained a maximum specific activity of 59.1 [units]/mg.

In the third Harris declaration, filed by Miles, Harris stated that his dissertation

> accurately reports [**32] on my work in which I was able to, and did, obtain a human VIII:C preparation having a potency of 193 [units]/ml and being substantially free of VIII:RP, the ratio of VIII:C to VIII:RP being greater than 100,000 times the ratio in plasma.

The third Harris declaration was cited by the district court in support of its finding of anticipation.

The parties debate whether Harris' statement in his second declaration that his product was chemically changed from naturally occurring VIII:C, is contradicted by the statement in his third declaration that he obtained a human VIII:C preparation. Scripps also points out that neither the potency value nor the ratio of VIII:C to VIII:RP described in the third Harris declaration appears

in the Harris dissertation. Nor does the gel pattern evidence on which the district court found that:

> Harris also based his identification of his preparation upon sodium dodecyl sulfate polyacrylamide gel electro-phoresis (SDS-PAGE) tests [the same tests used by Dr. Fulcher]. While Harris' gel patterns do not match the gel pattern found by Dr. Fulcher, there is no evidence that if he had VIII:C, it would necessarily have the gel pattern found by Dr. Fulcher.

[**33] *Scripps, 707 F. Supp. at 1551 n.6, 11 U.S.P.Q.2d at 1190 n.6.* Further, this finding that human Factor VIII:C, if obtained by Harris, would not necessarily have the "fingerprint" gel pattern of Dr. Fulcher, was not simply an adverse factual inference, improper on summary judgment; it was a finding of scientific fact contrary to the evidence. This finding also appears to be inconsistent with the court's finding that Dr. Harris had obtained purified Factor VIII:C because he based his identification on the same tests and gel patterns taught by Zimmerman and Fulcher. Also contradicting the court's conclusion was Scripps' evidence that the human Factor VIII:C SDS-gels of the inventors, the defendants, and non-parties to the litigation were the same, and that Dr. Harris' gel patterns were different.

Scripps contends that the court also erred in taking Dr. Harris' assertion in his third declaration that he obtained a potency of 193 units/ml and then construing the dissertation so as to find support for it. The court found support for this potency by combining (1) the potency of 2.7 units/ml reported by Harris for the sample in his Figure 9 with (2) the 71-fold concentration of an unidentified [**34] sample described on page 56 of the dissertation, and then multiplying 2.7 by 71 to obtain a potency of 191.7 units/ml. This combination of data is contrary to the statement of Dr. Harris in his second declaration that:

> [*1578] 15. Neither is there any information from which to infer that the LMW-AHF recovered in the experiment represented by Figure 9 was the subject of [the page 56] lyophilization and reconstitution experiment.

Scripps also states that the maximum potency that the dissertation disclosed was 10 units/ml. Even crediting Dr. Harris' assertion that the ratio of AHF (antihemophilic factor) to VWF (von Willebrand factor) may have been as high as 100,000:1, Scripps calculated that this would only increase the potency of the concentrated sample on Harris' page 56 to a maximum of 10.0 units/ml. A sample having the potency of 191.7 units/ml, the value found by the district court, was calculated by Scripps to have a theoretical ratio of no less than 1,917,000:1, over 19 times higher than that asserted by Dr. Harris in his dissertation. Scripps thus argues that the court's findings are contrary to the evidence. We need not decide the correctness of these calculations and their premises, [**35] for it is clear that these issues, on which there was conflicting evidence, were not subject to summary resolution.

To the extent that apparent inconsistencies among the three Harris declarations raise questions of credibility and weight, whether of witness or of interpretation of scientific data, they were improperly resolved on summary judgment. *Agosto v. INS, 436 U.S. 748, 756, 56 L. Ed. 2d 677, 98 S. Ct. 2081 (1977); Poller, 368 U.S. at 473.* [HN17] In patent cases, questions by affidavit is disfavored. *See Poller v. Columbia Broadcasting System, Inc., 368 U.S. 464, 473, 7 L. Ed. 2d 458, 82 S. Ct. 486 (1961); United States v. Fred A. Arnold, Inc., 573 F.2d 605, 606 (9th Cir. 1978).* Trial by document is an inadequate substitute for trial with witnesses, who are subject to examination and cross-examination in the presence of the decision-maker. *Sartor v. Arkansas Natural Gas Corp., 321 U.S. 620, 628, 88 L. Ed. 967, 64 S. Ct. 724 (1944).*

Scripps also raised the question of whether the Harris dissertation was enabling and placed the purported anticipatory teaching of purified Factor VIII:C in possession of the public. Scripps pointed out that Data in Harris' third declaration, on which the court relied, do not appear in his dissertation or in any other reference. [**36] *See Akzo N.V. v. United States Int'l Trade Comm'n, 808 F.2d 1471, 1479, 1 U.S.P.Q.2d (BNA) 1241, 1245 (Fed. Cir. 1986), cert. denied, 482 U.S. 909, 96 L. Ed. 2d 382, 107 S. Ct. 2490 (1987)* (anticipatory reference must be enabling); *In re Brown, 51 C.C.P.A. 1254, 329 F.2d 1006, 1011, 141 U.S.P.Q. (BNA) 245, 249 (CCPA 1964).* The need to consider this issue, on disputed factual premises, also negates the propriety of the grant of summary judgment based on anticipation.

The grant of partial summary judgment of invalidity of claims 24, 26, and 27 for anticipation by the Harris dissertation is reversed. The issue is not amenable to summary disposition, and is remanded for trial.

IV

Best Mode

The district court granted Genentech's motion for summary judgment that claims 13, 14, 17, 18, 24-29, and

34 are invalid for failure to comply with the "best mode" requirement of [HN18] *35 U.S.C. § 112:*

> § **112**. The specification shall . . . set forth the best mode contemplated by the inventor of carrying out his invention.

[HN19] Compliance with the best mode requirement is a question of fact, and invalidity for failure of compliance requires proof by clear and convincing evidence that the inventor knew of and concealed a better mode of carrying out the invention [**37] than was set forth in the specification. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1369, 1379, 231 U.S.P.Q. (BNA) 81, 90 (Fed. Cir. 1986), cert. denied, 480 U.S. 947, 94 L. Ed. 2d 792, 107 S. Ct. 1606 (1987).*

The concealment asserted by Genentech relates to the monoclonal antibodies that bind the Factor VIII complex in the initial step of separation from plasma. Genentech did not dispute that the specification describes the inventors' preferred method of obtaining these monoclonal antibodies. [*1579] The specification describes the process, starting with injection into mice of the commercial Factor VIII concentrate, to produce antibodies against Factor VIII:RP; the preparation of the hybridomas and their screening for the desired antibodies; and the method of evaluation of the antibody's ability to bind Factor VIII:RP in the presence of salt solution that disassociates Factor VIII:C. The specification describes the properties for which the antibodies were screened, *viz.* to obtain a monoclonal antibody to Factor VIII:RP, of the IgG class, which binds greater than 90% of the VIII:RP out of plasma or concentrate, and which remains bound to the VIII:RP during saline elution of Factor VIII:C.

None of this [**38] was criticized by Genentech. There was no charge of concealment of special manipulations, or undisclosed techniques. Genentech's argument is primarily that because of the laborious nature of the process of screening monoclonal antibodies, the inventors should have voluntarily placed in a depository and made available to the public the antibody to Factor VIII:RP designated 2.2.9, which was the first effective antibody obtained by Scripps' screening, and was used by Scripps in carrying out the claimed invention.

Scripps states that the procedures in the specification produce monoclonal antibodies having the characteristics set forth in the specification, that the process of obtaining these antibodies was fully disclosed, that the data in Table I are for the 2.2.9 antibody, and that the 2.2.9 antibody was not concealed. Scripps agreed that the 2.2.9 antibody was indeed the first that had the described properties, and states that three out of the first seven antibodies screened had these properties, all obtained by routine and admittedly time-consuming procedures. It was not disputed that the inventors obtained the 2.2.9 antibody by following the procedures in the patent specification, [**39] and that these were the inventors' preferred procedures.

The district court found that the inventors concealed the 2.2.9 antibody, and that this antibody was the best mode of carrying out the invention. The court did not hold that deposit of the 2.2.9 antibody was required, although the court stated that a person of skill in the art would not have known "where to obtain it". The court made no other finding relating to concealment.

A deposit was not required by the PTO during examination of either the '509 or the R *'011* patents. *See* M.P.E.P. § 608.01(p)(C)(3). Nor does Genentech argue that deposit was obligatory. No protester raised the issue of deposit in connection with the reissue application. Although Genentech suggests that Scripps should have made a deposit voluntarily, failure to do so can not constitute legal or factual basis for patent invalidity.

Despite the extensive attorney argument, there were no material facts in dispute. There was no evidence by Genentech that the antibodies used by Drs. Zimmerman and Fulcher differed from those obtainable according to the process described in the specification. The laborious nature of this work was recognized in *Hybritech, supra,* [**40] and again in *In re Wands, 858 F.2d 731, 737-38, 8 U.S.P.Q.2d (BNA) 1400, 1406-07 (Fed. Cir. 1988).* In *Wands* this court, considering the question of enablement, declined to require the deposit of antibody samples that could be obtained by screening following the procedures in the specification.

Genentech had argued to the PTO, in its Protest against the reissue application, that the process is "easily" carried out to produce "high affinity monoclonal antibodies":

> There are numerous references demonstrating the ease with which high affinity monoclonal antibodies could be obtained to Factor VIII:R[P].

In the context of best mode, on facts similar to those at bar, this court's holding in *Hybritech* settled the issue:

> The only evidence even colorably relating to concealment is testimony by various Hybritech employees that sophisticated, competent people perform the screening

> and that the screening process is labor-intensive and time-consuming. *It is not plausible that this evidence amounts to proof of concealment* of a best mode for [*1580] screening or producing monoclonal antibodies for use in the claimed '110 process, and therefore we are of the firm conviction that the district court's [**41] finding that the best mode requirement was not satisfied is clearly erroneous.

Hybritech, 802 F.2d at 1385, 231 U.S.P.Q. at 94 (emphasis added). Applying *Hybritech* to the undisputed facts, a finding of concealment can not be supported. The claims were incorrectly held invalid on this ground.

As a matter of law, we reverse the grant of partial summary judgment that claims 13, 14, 17, 18, 24-29, and 34 are invalid for failure to meet the best mode requirement. We remand with instructions that partial summary judgment be entered for Scripps on this ground.

V

Infringement

The district court found the R *'011* product claims 24, 25, 28, and 29 literally infringed, explaining that "Human factor VIII:C as claimed in the [product claims] therefore applies to any Factor VIII:C preparation, regardless of how produced, having the same material structural and functional characteristics as the plasma-derived preparation." The court did not distinguish between plasma-derived and recombinantly-produced human Factor VIII:C. n9 Genentech does not challenge this ruling as applied to plasma-derived VIII:C.

> n9 In accordance with the recombinant procedure, the human Factor VIII:C gene is identified, isolated, and inserted into a host cell, where it is replicated and from which Factor VIII:C is expressed and excreted into a culture medium. From this medium it is further purified using, *inter alia*, monoclonal antibodies to Factor VIII:C.

[**42]

A

Genentech appeals the district court's grant of Scripps' motion for summary judgment that the product claims are infringed by Genentech's recombinantly-produced human Factor VIII:C. Genentech states that the product claims should be construed, as a matter of law, to avoid infringement by recombinant VIII:C. Alternatively, Genentech argues that infringement is avoided by application of the reverse doctrine of equivalents. These two theories of non-infringement require different analytic approaches.

In "claim construction" the words of the claims are construed independent of the accused product, in light of the specification, the prosecution history, and the prior art. Of course the particular accused product (or process) is kept in mind, for it is efficient to focus on the construction of only the disputed elements or limitations of the claims. However, the construction of claims is simply a way of elaborating the normally terse claim language: in order to understand and explain, but not to change, the scope of the claims.

We described the workings of claim construction in *Tandon Corp. v. Int'l Trade Comm., 831 F.2d 1017, 1021, 4 U.S.P.Q.2d 1283, 1286 (Fed. Cir. 1987):*

> [HN20] Claim [**43] interpretation is a question of law, having factual underpinnings. When the meaning of key terms of claims is disputed . . . extrinsic evidence may be adduced including testimony of witnesses, and reference may be had to the specification, the prosecution history, prior art, and other claims.

Genentech argues that the term "a human VIII:C preparation" in the R *'011* product claims should be construed as limited to the Factor VIII:C obtained by separation from plasma. In essence, Genentech argues that these claims should be construed as carrying an inherent process limitation, on the basis that Scripps did not invent human Factor VIII:C, or discover its structure, or its properties as the coagulant factor in blood, but simply the process of purifying it to a higher degree of purity than was heretofore available. However, Genentech also states that it is not challenging the propriety of product claims to Factor VIII:C; and it did not do so before the district court. While judicial attention has on occasion focused on the patentability of claims in this context, *see, e.g., In re Bergstrom, 57 C.C.P.A. 1240, 427 F.2d 1394, 166 U.S.P.Q. (BNA) 256 (CCPA 1970),* Genentech, by conceding that [*1581] the product claims were [**44] appropriately granted, presents inconsistent legal arguments. Genentech has not supported, as a matter of law, its requested claim construction.

B

[HN21] The so-called "reverse doctrine of equivalents" is an equitable doctrine invoked in applying properly construed claims to an accused device. Just as the purpose of the "doctrine of equivalents" is to prevent "pirating" of the patentee's invention, *Graver Tank & Mfg. Co. v. Linde Air Prod. Co., 339 U.S. 605, 607, 608, 85 U.S.P.Q. (BNA) 328, 330, 94 L. Ed. 1097, 70 S. Ct. 854, reh'g denied, 340 U.S. 845, 95 L. Ed. 620, 71 S. Ct. 12 (1950),* so the purpose of the "reverse" doctrine is to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention.

[HN22] The reverse doctrine of equivalents flows from the Supreme Court's statement in *Graver Tank* that an accused article may avoid infringement, even if it is within the literal words of the claim, if it is "so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way." *339 U.S. at 608-09, 85 U.S.P.Q. at 330.* Application of the doctrine requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims, which [**45] in turn is determined in light of the specification, the prosecution history, and the prior art.

The record contained evidence of the properties of plasma-derived and recombinantly produced VIII:C, which was presented primarily by Scripps in connection with its proofs of infringement. There was deposition testimony that there were differences between VIII:C from plasma and VIII:C obtained by recombinant techniques; a Scripps' witness described the products as "apples and oranges", referring specifically to stability and formulations. The parties disputed, in connection with the summary judgment motions, the capabilities of the respective processes in terms of the purity and specific activities that were enabled for the respective products. The record on this point is extensive.

Genentech argues that its product is equitably seen as changed "in principle", particularly when viewed in the context of the prior art. Genentech asserts that the specific activities and purity that are obtainable by recombinant technology exceed those available by the Scripps process; an assertion disputed by Scripps, but which if found to be correct could provide -- depending on the specific facts of similarities [**46] and differences -- sufficient ground for invoking the reverse doctrine. These aspects were not discussed by the district court.

The principles of patent law must be applied in accordance with the statutory purpose, and the issues raised by new technologies require considered analysis. Genentech has raised questions of scientific and evidentiary fact that are material to the issue of infringement. Consideration of extrinsic evidence is required, and summary judgment is inappropriate. *See C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc., 911 F.2d 670, 673, 15 U.S.P.Q.2d (BNA) 1540, 1542 (Fed. Cir. 1990).*

The grant of summary judgment of infringement of claims 24, 25, 28, and 29 is reversed. The issue requires trial.

VI

Inducement to Infringe

The district court held that Genentech induced Cutter Laboratories to infringe claims 24, 25, 28, and 29 of the R *'011* patent, *35 U.S.C. § 271*(b), through the use of both plasma-derived and recombinant Factor VIII:C. The court held:

> There is no question that Genentech delivered to Cutter materials found to have infringed, including recombinant and plasma-derived human Factor VIII:C, with the intent that Cutter itself would [develop recombinant [**47] Factor VIII:C]. . . . There is also no doubt that Genentech intended Cutter to use plasma-derived Factor VIII:C manufactured by both Genentech and Cutter which has been found to infringe.

[*1582] *Scripps, 666 F. Supp. at 1394, 3 U.S.P.Q.2d at 1493.* The facts of the relationship between Genentech and Cutter were undisputed.

Genentech states that the district court made no specific finding of direct infringement by Cutter, a predicate to a finding of inducement to infringe. Cutter is a division of Miles, a defendant herein, and is subject to the district court's finding of infringement. Thus the court's ruling on inducement was correct, as a matter of law. Subject to our holding in Part V, the decision of the district court on this issue is affirmed.

VII

Inequitable Conduct based on the Meyer Abstract

Genentech appeals the district court's grant of summary judgment that Scripps did not engage in inequitable conduct, during examination of the application that led to the '509 patent, based on a reference authored by Meyer, Obert, Zimmerman, and Edgington entitled *Monoclonal Antibodies Specific for Factor VIII from Cellular Hybrids*, No. 395 ("the Meyer abstract").

The district court [**48] observed that the Meyer abstract was cumulative to the complete Meyer paper it summarized:

> The Meyer abstract was also cited in a paper authored, *inter alia*, by Dr. Meyer herself that was submitted by Scripps to the PTO as reference RS. . . . In contrast to the Meyer abstract, which is only one paragraph long, reference RS is 27 pages in length and much more elaborate in its disclosure . . . .

Scripps, 666 F. Supp. at 1399-1400, 3 U.S.P.Q.2d at 1496. [HN23] A reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct. *Halliburton Co. v. Schlumberger Technology Corp., 925 F.2d 1435, 1440, 17 U.S.P.Q. 2d (BNA) 1834 (Fed. Cir. 1991).*

The Meyer abstract was before the patent examiner who, according to Genentech, discovered it "on his own". When a reference has been considered by the examiner, it is not controlling how it came to the examiner's attention. The complete Meyer paper, and several other references, cited the Meyer abstract. Genentech argues that Scripps should nonetheless have brought the Meyer abstract to the examiner's specific attention, in addition to having listed the complete Meyer [**49] paper in Scripps' prior art statement. [HN24] When a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it can not be deemed to have been withheld from the examiner.

Genentech presses the argument that the district court erred because the Meyer abstract was a "statutory bar", by which Genentech explains that it was published more than a year before the patent's filing date. Genentech does not explain how this was error, for the district court, like the PTO, treated as prior art both the 27-page Meyer paper and the Meyer abstract. Genentech's argument that the full paper "was not effective prior art" is contrary to law and fact, for it was published before the filing date of Scripps' '509 patent application and Scripps did not attempt to antedate the Meyer paper. It is thus immaterial when the Meyer abstract was published.

Genentech also charged Scripps with inequitable conduct because Scripps originally sought claims to its monoclonal antibodies to Factor VIII:RP, and cancelled these claims after the examiner required Scripps to provide comparative data with the monoclonal antibodies described in the Meyer abstract and other references. [**50] While Genentech argues that obtaining such data was not the burden that Scripps said it was, this is irrelevant to the issue of inequitable conduct. An applicant has the absolute right to decline to do work suggested by the PTO, and to withdraw claims that had been presented for examination, without incurring liability for inequitable conduct.

The district court reviewed the Meyer abstract's content and found, without challenge on this appeal, that:

> [*1583] The Meyer et al. abstract contains no disclosure of the purification of Factor VIII:C. The Meyer et al. abstract contains no disclosure indicating that any of the monoclonal antibodies could be bound to substrate particles to form an immunoadsorbent for isolation and purification of VIII:C from the VIII:C/VIII:RP complex.

The court concluded:

> Lacking such disclosure, the Meyer et al. abstract does not appear material to the examination of the claims that were presented in applicants' original application and issued in Patent No. 4,361,509.

Scripps, 666 F. Supp. at 1398, 3 U.S.P.Q.2d at 1495. No error is ascribed to this conclusion. [HN25] A reference that is material only to withdrawn claims can not be the basis of a holding of inequitable [**51] conduct. *Kimberly-Clark Corp. v. Johnson & Johnson Co., 745 F.2d 1437, 1457, 223 U.S.P.Q. (BNA) 603, 616-17 (Fed. Cir. 1984).*

[HN26] The party with the burden of proof of inequitable conduct must meet the clear and convincing standard. *FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1417 n.11, 5 U.S.P.Q.2d (BNA) 1112, 1117 n.11 (Fed. Cir. 1987).* Genentech did not offer evidence or legal argument whereby, even drawing all factual inferences in its favor, this standard could be met at trial, as to either materiality of the Meyer abstract, or intent to deceive or mislead. The district court's grant of partial summary judgment of no inequitable conduct based on the Meyer abstract is affirmed.

VIII

Infringement of the Product-by-Process Claims

Scripps appeals the district court's refusal to grant its motion for summary judgment of infringement of the R

'011 product-by-process claims 13, 14, 17, 18, and 34. The district court denied Scripps' motion under Rule 59(e) to amend the judgment to rule on this question. Genentech argues that this denial is not appealable, and has moved for dismissal. [HN27] Looking to the law of the Ninth Circuit, an appeal from a final judgment may include challenges to "all rulings which [**52] produced the judgment". *Munoz v. Small Business Administration, 644 F.2d 1361, 1364 (9th Cir. 1981). See Moran v. Aetna Life Insurance Co., 872 F.2d 296, 301 (9th Cir. 1989)* (denial of a summary judgment motion is appealable after entry of final judgment); 10 C. Wright, A. Miller, and M. Kane, *Federal Practice & Procedure* § 2715 (2d ed. 1983). The issue is reviewable, but on an undeveloped record we consider only the questions of law.

Scripps charges that Genentech's recombinantly-produced Factor VIII:Cinfringes the product-by-process claims, either literally or by application of the doctrine of equivalents. The district court remarked that the product-by-process claims would not be infringed unless the same process were practiced. Scripps correctly points out that this statement appears to diverge from our precedent, recognizing that this precedent arose in the context of patent prosecution, not patent infringement. *E.g., In re Thorpe, 777 F.2d 695, 227 U.S.P.Q. (BNA) 964 (Fed. Cir. 1985)* (holding that prior art pertinent only to product is proper ground for rejecting product-by-process claims); *In re Brown, 59 C.C.P.A. 1036, 459 F.2d 531, 535, 173 U.S.P.Q. (BNA) 685, 688 (CCPA 1972)* (in product-by-process [**53] claims the patentability of the product must be established independent of the process); *In re Bridgeford, 53 C.C.P.A. 1182, 357 F.2d 679, 682 n.5, 149 U.S.P.Q. (BNA) 55, 58 n.5 (CCPA 1966)* (recognizing that some courts in infringement litigation have construed product-by-process claims as limited to the particular process, but holding that patentability is determined independent of the process). In determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of [HN28] product-by-process claims is that they are not limited to product prepared by the process set forth in the claims. Thus, these claims are subject to an infringement analysis similar to that described in Part V, [*1584] *ante*. Infringement of the product-by-process claims may be considered at trial.

IX

Attorney Fees

The district court held that this was an exceptional case under *35 U.S.C. § 285, 724 F. Supp. 690,* apparently due to the court's rulings on inequitable conduct and failure to comply with the best mode. Holdings under § 285 are reviewed for abuse of the trial court's discretionary authority, considering the court's findings [**54] and conclusions and any other appropriate factors. *See Reactive Metals & Alloys Corp. v. ESM, Inc., 769 F.2d 1578, 1583, 226 U.S.P.Q. (BNA) 821, 824 (Fed. Cir. 1985).* In view of our reversal of the grants of summary judgment on the issues of best mode and inequitable conduct, the award of attorney fees flowing therefrom must be vacated. *See State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1238, 224 U.S.P.Q. (BNA) 418, 426 (Fed. Cir. 1985)* (reversing ground for holding case exceptional and accompanying award of attorney fees).

X

Other Issues

We have not repeated all the arguments and issues raised by both sides, including charges of frivolity, misstatement, and worse. Encumbered by the summary nature of the proceedings, neither scientific nor evidentiary truth has risen easily to the surface. However, we *DENY* Scripps' motion for sanctions against Genentech for filing a frivolous cross-appeal, for some of the issues raised were not clearly hopeless in law and fact. We also *DENY* each side's motions to strike various materials filed and to dismiss issues raised by the other.

Costs

Each party shall bear its costs.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, AND REMANDED [**55]

LEXSEE

ATLAS POWDER COMPANY, Plaintiff, and HANEX PRODUCTS, INC., Plaintiff-Appellant, v. IRECO INCORPORATED and ICI EXPLOSIVES USA, INC., Defendants-Appellees.

99-1041

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

190 F.3d 1342; 1999 U.S. App. LEXIS 21394; 51 U.S.P.Q.2D (BNA) 1943

September 7, 1999, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court for the District of Wyoming. Chief Judge Alan B. Johnson.

DISPOSITION: AFFIRMED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant, as successor patent licensee, challenged United States District Court for District of Wyoming bench trial determination of invalidity of original and reissue patents as anticipated by two other patents.

OVERVIEW: A patent and its reissue (patents) declared invalid by the court involved explosive compositions. To address shortcomings in detonation, explosive experts developed water-in-oil emulsions that dissolved an oxidizer into water and then dispersed the solution in oil. The patents claimed composite explosives made from the combination of a particular blasting composition and an unsensitized water-in-oil emulsion. These were identical to blasting compositions of prior art issued two other companies. The only element arguably missing was the requirement that "sufficient aeration be entrapped to enhance sensitivity to a substantial degree." The appellate court affirmed the declaration of invalidity, finding there was no error in the court's conclusion that "sufficient aeration to enhance sensitivity" was understood by those of ordinary skill in the art to include both interstitial and porous air, or in its determination that the evidence clearly and convincingly established it was inherent in the two anticipating prior art references.

OUTCOME: Finding of invalidity affirmed, because district court correctly interpreted the claims and applied the law of anticipation. Nor was there clear error in factual determination that prior art inherently possessed sufficient aeration to enhance sensitivity to substantial degree within the overlapping ranges. Finding of non-infringement was not addressed.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Infringement > Claim Interpretation
[HN1] The appellate court reviews claim construction in patent contests as a matter of law.

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous ReviewPatent Law > Infringement > Claim Interpretation
[HN2] In patent contests, anticipation is a question of fact, including whether or not an element is inherent in the prior art. The appellate court reviews a finding of anticipation under the clearly erroneous standard.

Patent Law > Novelty & AnticipationPatent Law > Infringement > Claim Interpretation
[HN3] To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. Anticipation of a patent claim requires a finding that the claim at issue "reads on" a prior art reference.

Patent Law > Novelty & Anticipation
[HN4] When a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates

the claim. It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is "anticipated" if one of them is in the prior art. In chemical compounds, a single prior art species within the patent's claimed genus reads on the generic claim and anticipates.

Patent Law > Infringement > Claim Interpretation
[HN5] The focus in construing disputed terms in patent claim language is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean.

Patent Law > Infringement > Claim Interpretation
[HN6] To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art.

Patent Law > Infringement > Claim Interpretation
[HN7] Artisans of ordinary skill may not recognize the inherent characteristics or functioning of prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.

COUNSEL: Stanford B. Owen, Fabian & Clendenin, of Salt Lake City, Utah, argued for plaintiff-appellant, Hanex Products, Inc. With him on the brief were W. Cullen Battle,. Robert A. Garda, Jr., and Jon C. Martinson.

Gordon L. Roberts, Parsons Behle & Latimer, of Salt Lake City, Utah, argued for defendant-appellee, IRECO Incorporated and ICI Explosives USA, Inc. Of counsel on the brief was C. Kevin Speirs.

JUDGES: Before MAYER, Chief Judge, MICHEL and RADER, Circuit Judges.

OPINIONBY: RADER

OPINION: [*1343] RADER, Circuit Judge.

The United States District Court for the District of Wyoming determined that U.S. Patent No. *4,111,727* (the Clay patent) and its reissue, U.S. Patent No. RE *33,788* (the reissue patent) were invalid. Atlas Powder Company (Atlas), a licensee under those patents, sued IRECO Incorporated (IRECO) for infringement of the Clay patent. Following two bench trials, the district court concluded that both the original Clay patent and the reissue patent were invalid as anticipated by either U.S. Patent No. *3,161,551* (Egly) or U.K. Patent No. 1,306,546 (Butterworth). Because [**2] the district court correctly interpreted the claims and applied the law of anticipation, this court affirms the finding of invalidity.

I.

The Clay patent and its reissue both claim explosive compositions. To detonate, [*1344] explosives require both fuel and oxidizers. The oxidizer rapidly reacts with the fuel to produce expanding gases and heat - an explosion. Composite explosives mix various sources of fuel and oxygen. The most widely used and economical composite explosive is ammonium nitrate and fuel oil (ANFO). ANFO explosives mix about 94% by weight of ammonium nitrate (AN), the oxidizer, with 6% by weight of fuel oil (FO). The AN may include porous prills, dense prills, Stengel flakes, or crystalline AN. ANFO explosives have two primary disadvantages. First, wet conditions dissolve the AN and make the explosive unusable in damp settings. Second, ANFO is a relatively weak explosive because interstitial air occupies considerable space in the mixture, thereby decreasing the amount of explosive material per unit of volume.

To address these shortcomings, explosive experts developed water-in-oil emulsions. These emulsions dissolved the oxidizer into water and then dispersed the solution [**3] in oil. Because oil surrounds the oxidizer, it is resistant to moisture, thus solving one of the problems with ANFO. Emulsions also increased the explosive's bulk strength by increasing the density of explosive material in the mixture. Emulsions, however, also have a disadvantage. Emulsions will not detonate unless sensitized. Sensitivity of a blasting composition refers to the ease of igniting its explosion. Experts generally sensitize emulsions by using gassing agents or adding microballoons throughout the mixture. The gassing agents or microballoons provide tiny gas or air bubbles throughout the mixture. Upon detonation, the gas pockets compress and heat up, thereby igniting the fuel around them. In other words, the tiny gas or air bubbles act as "hot spots" to propagate the explosion.

The Clay patent and its reissue both claim composite explosives made from the combination of an ANFO blasting composition and an unsensitized water-in-oil emulsion. Both patents claim essentially the same blasting composition. Claim one of the reissue patent recites:

> 1. A blasting composition consisting essentially of 10 to 40% by weight of a greasy water-in-oil emulsion and 60 to 90% of [**4] a substantially undissolved particulate solid oxidizer salt constituent, wherein the emulsion comprises about 3 to 15% by weight of water, about 2 to 15% of oil, 70 to 90% of powerful oxidizer salt comprising ammonium nitrate which may include other powerful oxidizer salts, wherein the solid constituent comprises ammonium nitrate and in which sufficient aeration is entrapped to enhance sensitivity to a substantial degree, and wherein the emulsion component is emulsified by inclusion of 0.1 to 5% by weight, based on the total composition, of an [oil-in-water] water-in-oil emulsifier to hold the aqueous content in the disperse or internal phase.

(Underline added.)

When this lawsuit began, Atlas was the exclusive licensee under the Clay patent in the continental U.S. and Hawaii. Atlas commenced this lawsuit against IRECO in 1986, alleging infringement of the Clay patent. During the course of litigation, Dr. Robert Clay, the inventor, filed a reissue petition with the United States Patent and Trademark Office (PTO). Atlas then moved to stay the litigation pending resolution of the reissue application. The district court denied that motion and conducted a first bench trial [**5] on the issues of validity and infringement of the Clay patent in October 1986. Dr. Clay then requested suspension of prosecution of the reissue application by the PTO in February 1987. After waiting several years for a decision from the district court, Dr. Clay requested that the PTO reinstate the reissue proceedings in 1990. In January 1992, the Clay reissue patent issued upon surrender of the original patent. Later that [*1345] year, the district court rendered its findings and judgment regarding the validity and infringement of the Clay patent.

In its 1992 judgment, the district court found claims 1, 2, 3, 10, 12, 13, and 14 of the Clay patent invalid as anticipated by either one of two prior art references, Egly or Butterworth. Egly and Butterworth each disclose blasting compositions containing a water-in-oil emulsion and ANFO with ingredients identical to those of the Clay patents in overlapping amounts. The following chart illustrates the overlap between the explosive compositions disclosed in the prior art patents and the Clay reissue patent:

	Clay	Egly	Butterworth
Composition contents:			
Water-in-oil Emulsion	10-40%	20-67%	30-50%
Solid Ammonium Nitrate	60-90%	33-80%	50-70%
Emulsion contents:			
Ammonium Nitrate	70-90%	50-70%	65-85%
Water	about 3-15%	about 15-about 35%	2-27%
Fuel Oil	about 2-15%	about 5-about 30%	2-27%
Emulsifier	0.1-5%	about 1-5%	0.5-15%

The only element of the Clay patent claims which is arguably not present in the prior art compositions is "sufficient [**6] aeration . . . entrapped to enhance sensitivity to a substantial degree." The trial court determined that "sufficient aeration" was an inherent element in the prior art blasting compositions within the overlapping ranges. The district court also found that none of the accused products infringed any of the asserted claims. The 1992 judgment was not final, however, and specifically reserved a decision on the effect of the reissue patent for phase two of the case.

On September 22, 1993, the district court granted Hanex Products Inc.'s (Hanex) motion to intervene in the lawsuit. Hanex owns the two patents and had licensed them to Atlas. Hanex asserted the same claim of patent infringement against IRECO that Atlas had asserted, but also initiated a declaratory judgment action against ICI Explosives USA, Inc. (ICI), Atlas' successor-in-interest, seeking the sole right to control the litigation. In July 1994, the district court granted declaratory relief in favor of Hanex, against ICI, giving Hanex the sole right to control and direct the litigation on the two patents.

After the reissue patent issued, the district court conducted a second bench trial, in January 1996, on the issues of phase [**7] two. Specifically, the district court considered whether reissue affected its 1992 judgment. On September 25, 1998, the district court rendered its final judgment finding claims 1, 2, 3, 10, 12, 13, and 14 of the Clay reissue patent invalid as anticipated and finding that IRECO had not infringed any of the asserted claims. Despite the PTO's consideration of the Egly and Butterworth references during prosecution of the reissue, the district court concluded that IRECO had overcome the Clay reissue patent's presumption of validity under *35 U.S.C. § 282* (1994) by clear and convincing evidence. The district court noted that IRECO presented a great deal of testimonial and documentary evidence on inherent disclosures of the prior art that was not before the PTO in the [*1346] reissue proceeding. Hanex appealed to this court from the 1998 final judgment.

II.

[HN1] This court reviews claim construction as a matter of law. See *Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1451, 46 U.S.P.Q.2D (BNA) 1169, 1173 (Fed. Cir. 1998)* (en banc); *Markman v. Westview Instruments, Inc., 52 F.3d 967, 979, 34 U.S.P.Q.2D (BNA) 1321, 1326 (Fed. Cir. 1995)* (en banc). [HN2] Anticipation is [**8] a question of fact, including whether or not an element is inherent in the prior art. See *In re Schreiber, 128 F.3d 1473, 1477, 44 U.S.P.Q.2D (BNA) 1429, 1431 (Fed. Cir. 1997)*. Therefore, this court reviews a finding of anticipation under the clearly erroneous standard. See *Gechter v. Davidson, 116 F.3d 1454, 1457, 43 U.S.P.Q.2D (BNA) 1030, 1032 (Fed. Cir. 1997)*.

[HN3] "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber, 128 F.3d at 1477*. Anticipation of a patent claim requires a finding that the claim at issue "reads on" a prior art reference. See *Titanium Metals Corp. v. Banner, 778 F.2d 775, 781, 227 U.S.P.Q. (BNA) 773, 778 (Fed. Cir. 1985)*. In other words, if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art. See *id. at 781*. Specifically, [HN4] when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls [**9] within each of the ranges anticipates the claim. See *id. at 780-82* ("It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art."). In chemical compounds, a single prior art species within the patent's claimed genus reads on the generic claim and anticipates. See *In re Gosteli, 872 F.2d 1008, 1010, 10 U.S.P.Q.2D (BNA) 1614, 1616 (Fed. Cir. 1989)*.

As noted previously, both Egly and Butterworth disclose blasting compositions with ingredients identical to those of the Clay patent and its reissue in overlapping amounts. The only element which is arguably missing from the prior art is the requirement that "sufficient aeration [be] entrapped to enhance sensitivity to a substantial degree." To decide the issue of anticipation, therefore, the district court examined whether "sufficient aeration . . . to enhance sensitivity" was inherently part of the prior art compositions. That decision, in turn, required the trial court to interpret the claim term "sufficient aeration." By looking at the express language of the claims and [**10] the patent's written description, the district court concluded that the claim term "sufficient aeration" included both interstitial air (between oxidizer particles) and porous air (within the pores of oxidizer particles).

The first task of this court on appeal is to construe independently the disputed claim term. This question requires this court to determine whether the claim term "sufficient aeration" includes porous air, as the trial court determined. The claim term "sufficient aeration" does not limit the air content of the composition to interstitial air. Rather, the broad term "aeration" contains no qualitative limits on the kind of air exposure, only the quantitative limit that the air exposure be "sufficient" to enhance sensitivity. If the inventor intended "sufficient aeration" to carry qualitative limits, he also did not express that

intention in the patent's written description. The specification gives no explicit definition of the phrase "sufficient aeration . . . to enhance sensitivity," which appears in the patent for the first time in the claims.

[*1347] It is, of course, possible that the inventor did not include qualitative limits on the term "sufficient aeration" in the [**11] specification because those of ordinary skill in the art understand that only interstitial air enhances sensitivity and satisfies the claim's language. See *Autogiro Co. of Am. v. U.S., 181 Ct. Cl. 55, 384 F.2d 391, 397, 155 U.S.P.Q. (BNA) 697 (Ct. Cl. 1967)* ("Claims cannot be clear and unambiguous on their face."); *Markman, 52 F.3d at 986* [HN5] ("The focus in construing disputed terms in claim language is . . . on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."). The trial record, however, shows that those of ordinary skill in this art at the time the patent application was filed knew that both interstitial and porous air enhance sensitivity. Dr. Clay himself, the inventor of the patents in suit, testified that air from any source would contribute to the explosion of a heavy ANFO composition and, particularly, air trapped within the pores of porous prilled AN. Therefore, this court detects no error in the district court's conclusion that "sufficient aeration . . . to enhance sensitivity" is understood by those of ordinary skill in the art to include both interstitial and porous air. [**12] The district court appropriately construed the claims at issue to include aeration from both sources.

III.

Based on its correct interpretation of "sufficient aeration," the district court heard evidence on whether both interstitial and porous air were present and enhanced sensitivity in the prior art explosive compositions. Based on the evidence, the district court concluded that IRECO had shown the inherency of the disputed claim element in the prior art and overcome "the presumption of validity under *35 U.S.C. § 282* by providing clear and convincing evidence of invalidity." This court must determine whether the district court committed clear error by determining that the evidence clearly and convincingly established that "sufficient aeration . . . to enhance sensitivity" was inherent in either Egly or Butterworth.

[HN6] To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See *Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369, 21 U.S.P.Q.2D (BNA) 1321, 1328 (Fed. Cir. 1991).* However, a prior art reference may anticipate when the claim limitation or limitations [**13] not expressly found in that reference are nonetheless inherent in it. See id.; *Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 U.S.P.Q.2D (BNA) 1051, 1053 (Fed. Cir. 1987).* Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re King, 801 F.2d 1324, 1326, 231 U.S.P.Q. (BNA) 136, 138 (Fed. Cir. 1986).* Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See *Titanium Metals, 778 F.2d at 780.* [HN7] Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id. at 782.* However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *id. at 782* ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . ., by one who has discovered its . . . useful properties."); *Verdegaal Bros., 814 F.2d at 633.* [**14]

This court's decision in Titanium Metals illustrates these principles. See *Titanium Metals, 778 F.2d at 775.* In Titanium Metals, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and [*1348] titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." *Titanium Metals, 778 F.2d at 776.* A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." *Id. at 782.* This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or [**15] not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.

The trial record contains exhaustive evidence regarding the inherency of both interstitial and porous air in the Egly and Butterworth compositions within the overlapping ranges. The testimony from expert witnesses for both parties established that whether sufficient air is present in the explosive composition to facilitate detonation is a function of the ratio of the emulsion to the solid constituent. Dr. Clay testified that "if you mix porous prills, for example, with 30% typical water-in-oil emulsions, you're going to have air in there and it will

detonate." Another of Atlas' experts testified that a mixture of 30% of either an Egly or a Butterworth emulsion, mixed with 70% standard fertilizer grade porous AN would have interstitial air, assuming nothing was done to disturb the size distribution of the AN prills. The other experts agreed that the emulsions described in both Egly and Butterworth would inevitably and inherently have interstitial air remaining in the mixture up [**16] to a ratio of approximately 40% emulsion to 60% solid constituent. The expert testimony supports the district court's conclusion that "sufficient aeration" is inherent in both Egly and Butterworth.

The district court also relied on evidence from several tests which showed that "sufficient aeration . . . to enhance sensitivity" was inherently present within the overlapping ranges of the Clay patents and Egly and Butterworth. In tests conducted with porous prilled AN combined with FO, stable detonations were obtained in every 8" diameter bore hole test where the percentage of emulsion ranged from 30% to 42.5%. Butterworth specifically discloses the use of porous prilled AN. Butterworth, p. 3, ll. 35-50. These tests, therefore, support the finding that "the emulsions described by Butterworth, combined with the ratios of ANFO disclosed by Butterworth, would inevitably and inherently have interstitial air remaining up to approximately 40% emulsion." The district court also found that the solid AN disclosed in Egly would have included porous prills. These tests, therefore, further support the court's finding that "emulsions described in the Egly Patent, combined with either AN or ANFO, [**17] would inevitably and inherently have interstitial air remaining in the mixture up to approximately 40% emulsion to 60% solid constituent." This court discerns no clear error in the district court's conclusion that "sufficient aeration" was inherent in each anticipating prior art reference.

Because "sufficient aeration" was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of Dr. Clay's alleged invention - that air may act as the sole sensitizer of the explosive composition. An inherent structure, composition, or function is not [*1349] necessarily known. See, e.g., *In re King, 801 F.2d at 1327; Titanium Metals, 778 F.2d at 782.* Once it is recognized that interstitial and porous air were inherent elements of the prior art compositions, the assertion that air may act as a sole sensitizer amounts to no more than a claim to the discovery of an inherent property of the prior art, not the addition of a novel element. Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation. See *Titanium Metals, 778 F.2d at 782.* In addition, there [**18] was evidence that Butterworth did recognize the functioning of interstitial and porous air in sensitizing the composition. Butterworth recognizes the need for a gaseous sensitizer. Butterworth, p. 2, ll. 38-56. It teaches that the "sensitizer may be a gaseous sensitizer present in the composition in the form of gas bubbles or discrete particles containing an entrapped gas such as air." Id., p. 2, ll. 41-45. Although this typically suggests use of a gassing agent or microballoons, Butterworth expressly recognizes that in certain ranges (i.e., 50% to 70% by weight of ANFO) the mixture of porous prilled AN and FO alone provides the necessary sensitization. See id., p. 3, ll. 37-50. The district court found that Butterworth thus inherently appreciates that interstitial and porous air may serve as the necessary sensitizer. This court discerns no clear error in that finding.

In reaching this judgment, this court notes that Egly teaches away from air entrapment. Specifically, Egly teaches that it is desirable to "fill all spaces in between each particle to give added density." Egly, col. 1, ll. 26-27. This statement in Egly, however, does not defeat the district court's finding of [**19] anticipation for several reasons. First, Egly's teaching does not in any way discredit the trial court's alternative reliance on Butterworth for invalidation of the Clay patent and its reissue. More important, the statement in Egly is, in fact, only a showing that Egly did not recognize the function of the inherently present interstitial air. As noted previously, an insufficient scientific understanding does not defeat a showing of inherency. In fact, even in Egly itself, the only way taught for removing interstitial air is the addition of more emulsion. See id., col. 1, ll. 50-55. Egly, however, teaches the use of a broad range - between 20% and 67% by weight - of water-in-oil emulsion. See id., col. 3, ll. 21-24. While Egly compositions containing amounts approaching 67% by weight of water-in-oil emulsions may have little or no entrapped air, the evidence established that at emulsion levels below 40%, Egly compositions "inevitably and inherently" trap sufficient amounts of air to enhance sensitivity. This evidence included both substantial amounts of expert testimony and data showing extensive testing of Egly compositions.

Finally, although the record showed that special [**20] mixing techniques - such as grinding and screening the AN particles - remove interstitial air from the blasting compositions, Egly did not teach or suggest any such techniques. Thus, although Egly may have suggested removal of air, it nonetheless inherently contained interstitial aeration sufficient to enhance sensitivity when comprised of elements within the Clay patent ranges. Consequently, this court discerns no clear error in the district court's conclusion that Egly compositions within the range of the Clay patent claims inherently contain sufficient air to enhance sensitivity.

Based upon all the evidence, substantial amounts of which were not before the PTO in its reissue examination, the district court concluded that IRECO had proven

> clearly and convincingly that, unless extraordinary measures are taken to grind and screen ammonium nitrate, the existence of "interstitial air," or sufficient [*1350] aeration to sustain a stable detonation, is a function of the ratios of emulsion to solid constituent. Specifically, at ratios of 30% emulsion and 70% solid constituent, which are common to the Clay Patent, the Egly Patent, and the Butterworth Patent, there is inherently sufficient [**21] aeration to sustain a stable detonation, barring extraordinary efforts to grind and screen the ammonium nitrate used in the solid constituent.

This court discerns no clear error in the district court's factual determination that the prior art inherently possesses sufficient aeration to enhance sensitivity to a substantial degree within the overlapping ranges. Nor does this court discern clear error in the district court's finding of anticipation based on either Egly or Butterworth. To uphold the Clay patent and its reissue would preclude the public from practicing the prior art.

III.

In conclusion, this court affirms the district court's finding of invalidity with respect to claims 1, 2, 3, 10, 12, 13, and 14 of the Clay patent and the Clay reissue patent. This court therefore does not address the district court's additional finding of non-infringement.

COSTS

Each party shall bear its own costs.

AFFIRMED.

LEXSEE

IN RE SCHREIBER

97-1201

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

128 F.3d 1473; 1997 U.S. App. LEXIS 29099; 44 U.S.P.Q.2D (BNA) 1429

October 23, 1997, Decided

SUBSEQUENT HISTORY: [**1] Suggestion for Rehearing In Banc Declined and Rehearing Denied December 17, 1997, Reported at: *1997 U.S. App. LEXIS 37546.*

PRIOR HISTORY: Appealed from: Patent and Trademark Office Board of Patent Appeals and Interferences. (Serial No. 08/187,111).

DISPOSITION: AFFIRMED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant patent applicant claimed patents on a device for dispensing popcorn. The Patent Office denied four of the patent claims. Appellee Patent and Trademark Office Board of Patent Appeals and Interferences (board) upheld the rejections. The patent applicant sought review of the board's decision.

OVERVIEW: The patent applicant filed patent claims for a device that was conical shaped with a large opening that fit on a container and a smaller opening at the opposite end that allowed the popped popcorn to pass though a few kernels at a time when the device was attached to a popcorn container. The board found that a prior patent that disclosed a spout for nozzle-ready canisters anticipated some of the patent claims. The board also found that some of the patent claims were obvious to one of ordinary skill in the art. On appeal, the court ruled that the patent claims were inherent and anticipated by the prior patent. The court held that the recitation of a new intended use for the old product did not make claims to that old product patentable. The court also held that the board did not err in its determination that the patent claims were obvious.

OUTCOME: The court affirmed the order from the board that sustained a final rejection of the patent applicant's claims.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Novelty & Anticipation
[HN1] To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. Anticipation is an issue of fact, and the question whether a claim limitation is inherent in a prior art reference is a factual issue on which evidence may be introduced.

Patent Law > Novelty & Anticipation
[HN2] The recitation of a new intended use for an old product does not make a claim to that old product patentable. The discovery of a new property or use of a previously known composition, even when that property and use are not obvious from prior art, can not impart patentability to claims to the known composition.

Patent Law > Novelty & Anticipation
[HN3] The question whether a reference is analogous art is irrelevant to whether that reference anticipates. A reference may be from an entirely different field of endeavor than that of the claimed invention or may be directed to an entirely different problem from the one addressed by the inventor, yet the reference will still anticipate if it explicitly or inherently discloses every limitation recited in the claims.

Patent Law > Novelty & AnticipationPatent Law > Specification & Claims > Description Requirement
[HN4] A patent applicant is free to recite features of an apparatus either structurally or functionally. There is nothing intrinsically wrong with defining something by what it does rather than what it is]in drafting patent claims. Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

Evidence > Procedural Considerations > Inferences & PresumptionsPatent Law > Novelty & Anticipation
[HN5] When a prior patient establishes a prima facie case of anticipation the burden shifts to the patient applicant to show that the prior art structure did not inherently possess the functionally defined limitations of his claimed apparatus.

COUNSEL: Joseph B. Taphorn, of Poughkeepsie, New York, argued for appellant.

Joseph G. Piccolo, Associate Solicitor, Office of the Solicitor, Patent and Trademark Office, Department of Commerce, of Arlington, Virginia, argued for the appellee. With him on the brief were Nancy J. Linck, Solicitor, Albin F. Drost, Deputy Solicitor, and Karen A. Buchanan, Associate Solicitor.

JUDGES: Before NEWMAN, PLAGER, and BRYSON, Circuit Judges. Opinion for the court filed by Circuit Judge BRYSON. Dissenting opinion filed by Circuit Judge NEWMAN.

OPINIONBY: BRYSON

OPINION: [*1474] BRYSON, Circuit Judge.

Stephen B. Schreiber appeals the decision of the United States Patent and Trademark Office's Board of Patent Appeals and Interferences sustaining a final rejection of four claims of Schreiber's patent application. We affirm.

I

Schreiber's patent application claims a device for dispensing popped popcorn. The device is conically shaped with a large opening that fits on a container and a smaller opening at the opposite end that allows popped popcorn to pass through when the device is attached [**2] to a popcorn container and turned upside down. An embodiment disclosed in Schreiber's patent application is depicted below. [*1475]

[SEE ILLUSTRATION IN ORIGINAL].

Schreiber filed a number of claims, and the examiner allowed many of the claims. Claims 1, 2, 14, and 15 were finally rejected, however, and those claims are the subjects of this appeal. Claim 1 recites:

> A dispensing top for passing only several kernels of a popped popcorn at a time from an open-ended container filled with popped popcorn, having a generally conical shape and an opening at each end, the opening at the reduced end allows several kernels of popped popcorn to pass through at the same time, and means at the enlarged end of the top to embrace the open end of the container, the taper of the top being uniform and such as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container.

Claim 2 is similar to claim 1 but additionally recites that the top comprises a "means at the reduced end of the top to close-off the opening thereat." The other two claims, claims 14 and 15, depend from claims [**3] 1 and 2, respectively. Schreiber does not argue that claims 14 and 15 are patentable if claims 1 and 2 are not. Accordingly, because we affirm the rejection of claims 1 and 2, we need not address claims 14 and 15.

Claim 1 was rejected by the examiner under *35 U.S.C. § 102*(b) as being anticipated by Swiss Patent No. 172,689 to Harz. The Harz patent discloses "a spout for nozzle-ready canisters," which may be tapered inward in a conical fashion, and it states that the spout is useful for purposes such as dispensing oil from an oil can. The examiner explained that Harz discloses a conical dispensing top for an open-ended container and concluded that "the Harz top is clearly capable of dispensing popped popcorn." Figure 5 from Harz is depicted below. [*1476]

[SEE ILLUSTRATION IN ORIGINAL].

Claim 2 was rejected by the examiner under *35 U.S.C. § 103* as being unpatentable over the combination of Harz and U.S. Patent No. *3,537,623* to Fisher. The examiner stated that although Harz does not disclose a "means at the reduced end of the top to close-off the opening thereat," Fisher does. The examiner concluded that it would have been obvious to one of ordinary skill in the

art to modify [**4] Harz in view of Fisher in order to "seal[ ] the container contents from contaminates."

In response to the patent examiner's rejections, Schreiber submitted a declaration stating that the conical dispensing top depicted in figure 5 of Harz was incapable of "jamming up the popped popcorn before the end of the cone and permitting the dispensing of only a few kernels at a shake of a package when the top is mounted on the container." The examiner did not enter that declaration in the record because he believed it had not been properly submitted. When Schreiber appealed to the Board, the Board remanded the case to the examiner to consider the declaration. On remand, the examiner considered the declaration but found that it did not provide sufficient information to support Schreiber's assertion that a dispensing top built according to Harz does not inherently possess the functionally defined limitations recited in the claims.

Schreiber again appealed to the Board, which upheld the rejections. The Board first found that Harz discloses every limitation recited in claim 1. Several of the recitations in the claims, the Board concluded, merely set forth the function and intended use [**5] of the top and therefore did not require any structural feature other than those taught by Harz. The Board found that the structure disclosed by Harz is inherently capable of dispensing popcorn in the manner set forth in the claims, and that Schreiber's declaration did not provide enough details to prove that the structure disclosed by Harz is incapable of performing the claimed functions of Schreiber's invention.

In response to Schreiber's argument that the conical dispensing top disclosed in Harz is designed to dispense liquids such as oil, rather than solid items such as popcorn, and that it is not large enough to pass popcorn kernels, the Board noted that the Harz patent referred to the use of the claimed device for lubricating oil only as an "example," and found that one of skill in the art "would perceive the top of Harz as being of broader application." The Board further found that the dispensing top disclosed in Harz "is of a relative size and has a taper which would inherently permit popped popcorn kernels to jam up before the end of the cone and permit the dispensing of only a few kernels at a [*1477] shake of the package" when the top is mounted on a popped popcorn container. [**6] Accordingly, the Board concluded that "all the limitations of claim 1 are found in Harz, either expressly or under the principles of inherency, and this claim is clearly anticipated thereby."

As for claim 2, the Board found that Fisher disclosed a means for closing off the smaller end of a conically shaped top and further found that it would have been obvious to one of ordinary skill in the art to provide a close-off mechanism for a top of the sort disclosed by Harz, to prevent dirt and other contaminating matter from entering the opening in the device. Schreiber appeals both of the Board's determinations.

II

Schreiber first argues that Harz does not anticipate claim 1. [HN1] To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. See *Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047, 34 U.S.P.Q.2D (BNA) 1565, 1567 (Fed. Cir. 1995).* Anticipation is an issue of fact, see *In re Graves, 69 F.3d 1147, 1151, 36 U.S.P.Q.2D (BNA) 1697, 1700 (Fed. Cir. 1995); Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677, 7 U.S.P.Q.2D (BNA) 1315, 1317 (Fed. Cir. 1988),* and the question whether a claim limitation is inherent in a [**7] prior art reference is a factual issue on which evidence may be introduced, see *Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991).*

There is no dispute that the structural limitations recited in Schreiber's application are all found in the Harz reference upon which the examiner and the Board relied. Thus, to use the terms found in Schreiber's claim 1, Harz discloses a "dispensing top" that has "a generally conical shape and an opening at each end," and "means at the enlarged end of the top to embrace the open end of the container, the taper of the top being uniform." Schreiber argues, however, that Harz does not disclose that such a structure can be used to dispense popcorn from an open-ended popcorn container.

Although Schreiber is correct that Harz does not address the use of the disclosed structure to dispense popcorn, the absence of a disclosure relating to function does not defeat the Board's finding of anticipation. It is well settled that [HN2] the recitation of a new intended use for an old product does not make a claim to that old product patentable. See *In re Spada, 911 F.2d 705, 708, 15 U.S.P.Q.2D (BNA) 1655, 1657 (Fed.* [**8] *Cir. 1990)* ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition."); *Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782, 227 U.S.P.Q. (BNA) 773, 778 (Fed. Cir. 1985)* (composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); *In re Pearson, 494 F.2d 1399, 1403, 181 U.S.P.Q. (BNA) 641, 644 (CCPA 1974)* (intended use of an old composition does not render

composition claim patentable); *In re Zierden, 56 C.C.P.A. 1223, 411 F.2d 1325, 1328, 162 U.S.P.Q. (BNA) 102, 104 (CCPA 1969)* ("Mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."); *In re Sinex, 50 C.C.P.A. 1004, 309 F.2d 488, 492, 135 U.S.P.Q. (BNA) 302, 305 (CCPA 1962)* (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus); *In re Hack, 44 C.C.P.A. 954, 245 F.2d 246, 248, 114 U.S.P.Q. (BNA) 161, 162 (CCPA 1957)* ("the grant of a patent on a composition or a machine cannot be predicated on a new use of that machine or composition"); *In re Benner, 36 C.C.P.A. 1081, 174 F.2d 938, 942, 82* [**9] *U.S.P.Q. 49, 53 (CCPA 1949)* ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product"). Accordingly, Schreiber's contention that his structure will be used to dispense popcorn does not have patentable weight if the structure is already known, regardless of whether it has ever been used in any way in connection with popcorn.

Schreiber makes the closely related argument that Harz does not anticipate claim 1 because Harz is non-analogous art to which one of ordinary skill in the art would not have looked in addressing the problem of dispensing tops for popped popcorn containers. [*1478] However, [HN3] the question whether a reference is analogous art is irrelevant to whether that reference anticipates. See *In re Self, 671 F.2d 1344, 1350, 213 U.S.P.Q. (BNA) 1, 7 (CCPA 1982).* A reference may be from an entirely different field of endeavor than that of the claimed invention or may be directed to an entirely different problem from the one addressed by the inventor, yet the reference will still anticipate if it explicitly or inherently discloses every limitation recited in the claims.

Schreiber further argues that the functional limitations of his [**10] claim distinguish it from Harz. In particular, Schreiber points to the recitation that the claimed top "allows several kernels of popped popcorn to pass through at the same time," and that the taper of the top is such "as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container."

[HN4] A patent applicant is free to recite features of an apparatus either structurally or functionally. See *In re Swinehart, 58 C.C.P.A. 1027, 439 F.2d 210, 212, 169 U.S.P.Q. (BNA) 226, 228 (CCPA 1971)* ("There is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. As our predecessor court stated in *Swinehart, 439 F.2d at 213, 169 U.S.P.Q. (BNA) at 228:*

> where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter [**11] shown to be in the prior art does not possess the characteristic relied on.

See also *In re Hallman, 655 F.2d 212, 215, 210 U.S.P.Q. (BNA) 609, 611 (CCPA 1981); In re Ludtke, 58 C.C.P.A. 1159, 441 F.2d 660, 663-64, 169 U.S.P.Q. (BNA) 563, 565-67 (CCPA 1971).*

The examiner and the Board both addressed the question whether the functional limitations of Schreiber's claim gave it patentable weight and concluded that they did not, because those limitations were found to be inherent in the Harz prior art reference. To begin with, contrary to the characterization in the dissent, nothing in Schreiber's claim suggests that Schreiber's container is "of a different shape" than Harz's. In fact, as shown above, an embodiment according to Harz (Fig. 5) and the embodiment depicted in figure 1 of Schreiber's application have the same general shape. For that reason, the examiner was justified in concluding that the opening of a conically shaped top as disclosed by Harz is inherently of a size sufficient to "allow[] several kernels of popped popcorn to pass through at the same time" and that the taper of Harz's conically shaped top is inherently of such a shape "as to by itself jam up the popped popcorn before the end [**12] of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container." The examiner therefore correctly found that Harz established a prima facie case of anticipation.

[HN5] At that point, the burden shifted to Schreiber to show that the prior art structure did not inherently possess the functionally defined limitations of his claimed apparatus. See *In re Spada, 911 F.2d at 708, 15 U.S.P.Q.2D (BNA) at 1658; In re King, 801 F.2d 1324, 1327, 231 U.S.P.Q. (BNA) 136, 138-39 (Fed. Cir. 1986); In re Best, 562 F.2d 1252, 1254-55, 195 U.S.P.Q. (BNA) 430, 433 (CCPA 1976).* The Board found that Schreiber failed to do so, and we agree. Schreiber's declaration asserts that he built a conically shaped top according to figure 5 of Harz and that it was too small to jam and dispense popcorn as recited in the claim. The declaration, however, does not specify the dimensions of either the

dispensing top that was tested or the popcorn that was used.

Moreover, the Board found as a factual matter that the top disclosed in figure 5 of the Harz patent "is capable of functioning to dispense kernels of popped popcorn in the manner set forth in claim 1." Starting with Schreiber's [**13] assumption that Harz should be limited to use as an attachment to an oil can, the Board scaled figure 5 to the proportions necessary to fit the Harz container on top of a standard one-quart oil can, as Schreiber suggested in his request for reconsideration. After scaling the Harz figure in that manner, the Board found that the Harz dispenser [*1479] would be capable of dispensing popcorn in the manner set forth in claim 1 of Schreiber's application.

The dissenting opinion incorrectly states that the Board "used Mr. Schreiber's invention as a template" in determining that the Harz dispenser anticipates Schreiber's invention. In fact, the Board simply scaled the dispenser illustrated in Harz figure 5 up to the size necessary to fit a standard oil can, without changing the proportions of the figure in any way. (The top depicted in figure 5 of the Harz patent was obviously not intended to be a full-sized representation of the Harz invention, any more than the top depicted in figure 1 of Schreiber's application was intended to be a full-sized representation of his invention.) The portion of the dissenting opinion addressed to this point is therefore based on a false premise - that the prior [**14] art device was "altered by the Board and then found to anticipate a different invention in whose image it was recreated." The Board's finding that the scaled-up version of figure 5 of Harz would be capable of performing all of the functions recited in Schreiber's claim 1 is a factual finding, which has not been shown to be clearly erroneous. On this ground alone, the Board's anticipation ruling must be upheld.

In any event, however, it is not enough for Schreiber to contend that a top built according to the proportions of figure 5 of Harz is incapable of performing the jamming and dispensing functions. The figures from Harz were provided only as "design examples of the invention"; the disclosure of the Harz patent is thus much broader than the precise conical shape disclosed in figure 5. Moreover, contrary to Schreiber's suggestion, the structure disclosed in Harz is not limited to use as an oil can dispenser. While that use is given as the principal example of the uses to which the invention could be put, nothing in the Harz patent suggests that the invention is in any way limited to that use. In sum, Schreiber's declaration fails to show that Harz inherently lacks the functionally [**15] defined limitations recited in claim 1 of the application. Accordingly, we agree with the Board that Schreiber has failed to rebut the prima facie case of anticipation identified by the examiner. The Board's factual finding on the issue of anticipation is therefore affirmed.

III

Schreiber also challenges the Board's finding that claims 2 and 15 are unpatentable under *35 U.S.C. § 103* as being obvious over the combination of Harz and Fisher. Schreiber argues that the combination of Harz and Fisher does not disclose all the limitations of claim 2 because neither Harz nor Fisher discloses the functionally defined features of the top. That argument is without merit because, as we have already noted, Harz discloses those functionally defined limitations.

Schreiber also argues that Fisher does not provide the function that the "means for closing off" in Schreiber's application provides. The functions Schreiber cites - enabling a person to carry a popped-popcorn package in a non-upright position without spillage, keeping the popcorn warm, and facilitating the mixing of ingredients - are not recited as part of the means-plus-function clause in claim 2. Accordingly, those functions cannot [**16] impart patentability to the claim.

Schreiber further argues that Fisher is non-analogous art because Fisher relates to pouring oil from an oil can whereas Schreiber's invention relates to popcorn dispensing. That argument was not raised before the Board and we therefore decline to consider it for the first time on appeal. Even if we were to consider that argument, however, we note that Schreiber acknowledges in the specification that the prior art pertinent to his invention includes patents relating to dispensing fluids. Schreiber therefore may not now argue that such patents are non-analogous art. See *Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1570, 7 U.S.P.Q.2D (BNA) 1057, 1063 (Fed. Cir. 1988); In re Fout, 675 F.2d 297, 300, 213 U.S.P.Q. (BNA) 532, 535 (CCPA 1980); In re Wood, 599 F.2d 1032, 1036, 202 U.S.P.Q. (BNA) 171, 174 (CCPA 1979); In re Nomiya, 509 F.2d 566, 571, 184 U.S.P.Q. (BNA) 607, 611-12 (CCPA 1975).* Accordingly, we find no error in the Board's [*1480] determination that claims 2 and 15 would have been obvious.

AFFIRMED.

DISSENTBY: NEWMAN

DISSENT: NEWMAN, Circuit Judge, dissenting.

I respectfully dissent. The panel majority affirms the PTO position that the express limitations [**17] of the claims are irrelevant when dealing with a rejection on the

ground of "anticipation." The court thus departs from the rules of claim interpretation on which we have placed so much weight. The Federal Circuit has held, over and over, that every claim limitation is important and none can be ignored -- and now proceeds to ignore several express limitations. Thus the panel incongruously holds that a claim that requires, explicitly and precisely, a container of popcorn and a dispenser that passes only a few kernels of popcorn before jamming, is "anticipated" by an oil can of a different shape as illustrated in a reference that neither shows nor suggests a container filled with popcorn or the jamming of the dispenser upon dispensing the popcorn. I feel for those who tread the arcane path of patent soliciting, for this court's insistence on the importance of the limitations in the claims seems to have lost its way.

Schreiber's claims 1 and 14 are representative:

> 1. A dispensing top for passing only several kernels of a popped popcorn at a time from an open-ended container filled with popped popcorn, having a generally conical shape and an opening at each end, the opening at the [**18] reduced end allows several kernels of popped popcorn to pass through at the same time, and means at the enlarged end of the top to embrace the open end of the container, the taper of the top being uniform and such as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container.
>
> 14. A package consisting of a container having popped popcorn and having an open end and embracing thereat a dispensing top according to claim 1.

The Board held that it is irrelevant that the Schreiber claims are limited to a container filled with popped popcorn with the additional limitation of dispensing a few kernels at a time before the dispenser jams up. No popcorn container or dispenser was cited by the PTO, and no similar claim limitations were cited by the PTO. These claim limitations can not be ignored. See *Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1532, 3 U.S.P.Q.2D (BNA) 1321, 1324 (Fed. Cir. 1987)* (the court can not ignore a plethora of meaningful limitations). Patentability is determined for the invention as claimed, with all its limitations. It is improper to [**19] delete explicit limitations from the claim in order to find the residue in the prior art.

"That which infringes if later anticipates if earlier." *Polaroid Corp. v. Eastman Kodak Co., 789 F.2d 1556, 1573, 229 U.S.P.Q. (BNA) 561, 574 (Fed. Cir. 1986)* (citing *Peters v. Active Mfg. Co., 129 U.S. 530, 537, 32 L. Ed. 738, 9 S. Ct. 389 (1889))*. It is inconceivable that this or any court would find Mr. Schreiber's claims to this popcorn dispenser infringed by the oil can of the Harz reference. The claim limitations that the container is filled with popped popcorn and that only a few kernels of popcorn are released at a time could not be ignored in an infringement action, and they are not properly ignored in a patentability action.

The Board, using Mr. Schreiber's invention as a template, rescaled the prior art and filled the oil can with popcorn. This exercise of hindsight is not "anticipation." The law of anticipation requires that the same invention, with all the limitations of the claims, existed in the prior art. See *Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2D (BNA) 1913, 1920-21 (Fed. Cir. 1989)* ("anticipation" requires that the identical invention is described in a single prior art reference). A [**20] prior art device can not be altered by the Board and then found to anticipate a different invention in whose image it was recreated.

In responding to the PTO's rejection, Mr. Schreiber made an actual conical top according to the Harz oil can's proportions, and reported that the popcorn did not behave as in his device. The Board then proposed that [*1481] Mr. Schreiber had erred in determining the diameter of the opening, and postulated that with the appropriate opening the Harz oil can might behave as does Mr. Schreiber's container. Mr. Schreiber says this is incorrect. I say it is irrelevant. See, e.g., *Richardson, 868 F.2d at 1236, 9 U.S.P.Q.2D (BNA) at 1920* (every element of the claim must be shown in the reference, including all limitations); *In re Paulsen, 30 F.3d 1475* (the reference must describe the claimed invention sufficiently to place it in the possession of a person of ordinary skill in the field).

Mr. Schreiber's popcorn dispenser is not described in the prior art. Statements in the claims that define and limit the device are material limitations, for purposes of infringement and for purposes of distinguishing from the prior art. See, e.g., *Rowe v. Dror, 112* [**21] *F.3d 473, 478-79, 42 U.S.P.Q.2D (BNA) 1550, 1553-54 (Fed. Cir. 1997)* (the field of the invention as stated in a Jepson-type claim limits the invention); *Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677-78, 7 U.S.P.Q.2D (BNA) 1315, 1317 (Fed. Cir. 1988)* (limitations stated in the preamble limit the claimed invention); *In re Stencel, 828 F.2d 751, 754-55, 4 U.S.P.Q.2D (BNA) 1071, 1073 (Fed. Cir. 1987)* (function stated in claim distinguishes from prior art). The rejection for lack of novelty is simply incorrect.

In *Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 137 L. Ed. 2d 146, 117 S. Ct. 1040 (1997)* the Court stressed the importance of claim limitations. The cases cited by the panel majority relate to the discovery of a new use of a known composition or device, and hold that the discovery of that use does not render patentable that which is already known. However, Schreiber's device is not known, but is new, and the claims are explicitly so limited. See *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1255-57, 9 U.S.P.Q.2D (BNA) 1962, 1965-66 (Fed. Cir. 1989)* ("To read the claim in light of the specification indiscriminately to cover all types of optical fibers would be divorced from reality."); [**22] *W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540* or *842 F.2d 1275* (anticipation can not be based on conjecture). The claimed popcorn dispenser having a novel structure and function, whereby the container is filled with popcorn and after a few kernels of popcorn are released the dispenser jams up, is not in the cited prior art. The explicit claim limitations must be considered in determination of anticipation, just as they would be considered in construing the claims for the purpose of determining infringement. They can not be ignored.

Since no prior art shows this device, it can not be "anticipated" as lacking novelty.

B

The panel majority suggests that it would be "inherent" to use the oil can as a popcorn dispenser. An inherent disclosure, to be invalidating as an "anticipation," is a disclosure that is necessarily contained in the prior art, and would be so recognized by a person of ordinary skill in that art. *Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268-69, 20 U.S.P.Q.2D (BNA) 1746, 1749-50 (Fed. Cir. 1991).* "Inherency" charges the inventor with knowledge that would be known to the art, although not described. Inherency is not a matter of hindsight [**23] based on the applicant's disclosure: the missing claim elements must necessarily be present in the prior art.

The authority cited by the majority, relating to claiming a known composition or device based on discovery of a new use, is inapt. It is of course correct that the discovery of a new use of a known composition or device does not render that composition or device patentable per se. The reason, however, is not "inherency"; it is that the composition or device is already known to the public, and can not be removed from the public. (The new use can of course be claimed as a method of use.) In this case, however, Mr. Schreiber has created a new device, not previously known to the public, and has claimed his new device with explicit limitations that distinguish it from previously known devices.

In passing, I also observe that the majority errs in stating that advantages not recited in the claim can not impart patentability to a new device. The advantages of an invention are often relied on to support patentability; whether they are included in the claim depends on a variety of factors, and is not the subject of a rigid rule.

[*1482] The issue in this case is anticipation; that is, novelty. [**24] Since the claimed invention is not described in a single prior art reference, it is not "anticipated."

LEXSEE

SCHERING CORPORATION, Plaintiff, v. PRECISION-COSMET CO., INC., Defendant

Civil Action No. 83-829-WKS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

614 F. Supp. 1368; 1985 U.S. Dist. LEXIS 18262; 227 U.S.P.Q. (BNA) 278

July 2, 1985

CASE SUMMARY:

PROCEDURAL POSTURE: This patent infringement matter came before the court on the following post-trial motions: defendant's motion for judgment notwithstanding the verdict and, in the alternative, for a new trial; and plaintiff's motion for an award of prejudgment interest, increased damages, and reasonable attorney's fees.

OVERVIEW: In a patent infringement action, the jury returned a general verdict for plaintiff along with answers to interrogatories, including a finding that defendant's infringement was willful. This matter came before the court on the following post-trial motions: defendant's motion for judgment notwithstanding the verdict and, in the alternative, for a new trial; and plaintiff's motion for an award of prejudgment interest, pursuant to *35 U.S.C.S. § 284;* increased damages, pursuant to *35 U.S.C.S. § 284;* and reasonable attorney's fees, pursuant to *35 U.S.C.S. § 285.* Court denied defendant's motion for judgment notwithstanding the verdict or a new trial. Court granted plaintiff's motion, awarding plaintiff double the damages found by the jury, interest from the time each reasonable royalty payment would have been made until the date of judgment, and attorney's fees in an amount to be agreed upon or determined by the court.

OUTCOME: Court denied defendant's motion for judgment notwithstanding verdict or new trial. Court granted plaintiff's motion, awarding plaintiff double damages found by jury, interest from time each reasonable royalty payment would have been made until date of judgment, and attorney's fees in amount to be agreed upon or determined by court.

LexisNexis (TM) HEADNOTES - Core Concepts:

Civil Procedure > Trials > Judgment as Matter of Law
[HN1] The moving party is entitled to a judgment notwithstanding the verdict (JNOV) when the court is convinced: (1) that reasonable persons could not in light of the evidence have found the facts necessary to support the jury's verdict; or (2) that the facts properly found cannot in law support that verdict. If, on the other hand, the court is convinced that reasonable persons could have found in light of the evidence the facts necessary to support in law the jury's verdict, denial of the motion for JNOV is required.

Civil Procedure > Trials > Judgment as Matter of Law
[HN2] The Federal Circuit has set forth guidelines that a court must follow in considering a motion for judgment notwithstanding the verdict. Under these guidelines, a court must: (1) consider all the evidence; (2) in a light most favorable to the non-mover; (3) drawing reasonable inferences favorable to the non-mover; (4) without determining credibility of witnesses; and (5) without substituting its choice for that of the jury between conflicting elements in the evidence.

Civil Procedure > Trials > Judgment as Matter of LawPatent Law > Infringement > Defenses
[HN3] Where the issue raised is validity, the true question is whether defendant, which bore the burden, *35 U.S.C.S. § 282,* submitted such evidence as would preclude a reasonable jury from reaching a verdict of validity. In this regard, it is well to note that the question

presented by a motion for judgment notwithstanding the verdict is not whether the district court would have found the invention obvious as though there had been no trial before a jury. Rather, the question is whether the jury's verdict that the patent is valid (i.e. has not been proved invalid) is supported by substantial evidence.

Patent Law > Nonobviousness > Tests & Proof of ObviousnessCivil Procedure > Jury Trials > Province of Court & Jury

[HN4] Though obviousness is a question of law, it is an issue that may properly be submitted to a jury, in the same manner that other legal questions, such as negligence, are regularly submitted to juries in personal injury cases.

Civil Procedure > Jury Trials > Province of Court & Jury

[HN5] The jury is entitled to reject a witness's testimony if they do not find it credible. And it is not the province of the court to weigh the credibility of a witness's testimony against the testimonies of other witnesses.

Patent Law > Novelty & AnticipationPatent Law > Infringement > Burdens of Proof

[HN6] A party asserting that a patent claim is anticipated under *35 U.S.C.S. § 102* must demonstrate identity of invention. Identity of invention is a question of fact, and one who seeks such a finding must show that each element of the claim in issue is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice.

Patent Law > Novelty & Anticipation

[HN7] The general rule is that a prior genus does not anticipate a later species. If, however, it is possible to derive a class of compounds of lesser scope than the genus disclosed in a prior art reference on the basis of preferences ascertainable from the remainder of the reference, anticipation may be found. The anticipating reference must contain within its four corners a sufficient description to enable one to practice the invention without experimentation or inventive skill. The test is whether the prior art reference describes the invention with sufficient clarity and specificity so that one skilled in the art may practice the invention without assistance from the patent claimed to have been anticipated.

Patent Law > Novelty & Anticipation

[HN8] A new use for an old substance is not patentable.

Patent Law > Novelty & Anticipation

[HN9] The rule that no product patent may issue for discovery of a new use for an old product or process is tempered by the doctrine of slight changes. The doctrine of slight changes extends to the area of chemical compounds. The modification of an old compound into a new patentable one may be slight.

Patent Law > Novelty & Anticipation

[HN10] A mere change in the amount of a compound has been deemed sufficient to change an old composition into a new one.

Patent Law > Specification & Claims > Claim Preambles

[HN11] The Court of Claims and Patent Appeals set down guidelines for determining when the introductory phrase of a claim would be permitted to limit the claim itself. The court indicated that the preamble would be permitted to limit a claim where it was deemed essential to point out the invention defined by the claim or count, that is, where the preamble was considered necessary to give life, meaning, and vitality to the claims or counts.

Patent Law > Specification & Claims > Claim Preambles

[HN12] The Court of Appeals for the Federal Circuit has looked to the preamble when necessary to give meaning to the claim and properly define the invention.

Patent Law > Infringement > Claim Interpretation

[HN13] Claims should be so construed, if possible, as to sustain their validity.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN14] While it is true that close structural similarity between prior art compounds and those that are claimed may be an indicia of obviousness, the subject matter of the invention as a whole may be non-obvious if the claimed compound has unexpected properties.

Civil Procedure > Trials > Judgment as Matter of LawCivil Procedure > Relief From Judgment > Motions for New Trial

[HN15] A motion for a new trial differs from a motion for judgment notwithstanding the verdict in that a motion for a directed verdict or for judgment notwithstanding the verdict raises the legal sufficiency of the evidence, and is to be sharply distinguished from a motion for a new trial on the ground that the verdict is against the weight of the evidence. The latter motion is addressed to the sound discretion of the trial court, which may set aside the verdict as contrary to the preponderance of the evidence although a directed verdict or judgment notwithstanding the verdict is not justified.

Civil Procedure > Relief From Judgment > Motions for New Trial
[HN16] The standard of review in considering a motion for a new trial is most often formulated in one of three ways. Thus, a new trial will be granted if the verdict is against the clear weight of the evidence, or if the court is convinced the jury has reached a seriously erroneous result, or if there has been a miscarriage of justice.

Patent Law > Infringement > Burdens of Proof
[HN17] The burden is on the patent holder to prove damages by a reasonable probability.

Civil Procedure > Jury Trials > Jury InstructionsCivil Procedure > Relief From Judgment > Motions for New Trial
[HN18] The standard of review of jury instructions on a motion for a new trial is as follows: Instructions must be viewed in their entirety. A new trial is permissible when it is clear that error in the instructions as a whole was such as to have misled the jury. In addition, the error must prejudice the defendant's case.

Patent Law > Novelty & Anticipation
[HN19] The presumption that the inventor has knowledge of all the art has been rejected by the Court of Appeals for the Federal Circuit.

Civil Procedure > Jury Trials > Jury Instructions
[HN20] Where a party has failed to make any request for an instruction with regard to knowledge of the ordinary person skilled in the art, under Fed. R. Civ. P. 51, that party has waived any objection based on that omitted instruction.

Patent Law > Infringement > Exclusive Rights
[HN21] Where a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing. Such an affirmative duty includes, inter alia, the duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity.

Patent Law > Infringement > Exclusive RightsPatent Law > Infringement > Defenses
[HN22] While counsel's opinion with respect to a patent is evidence of good faith, it is not dispositive, and it is necessary to look at the totality of circumstances presented by a case in determining whether infringement is willful. Willfulness may include a determination that the infringer had no reasonable basis for believing it had a right to do the acts.

Patent Law > Infringement > Exclusive RightsPatent Law > Infringement > Defenses
[HN23] A memorandum containing only bold, conclusory, and unsupported remarks regarding validity is inadequate for reasonable reliance.

Patent Law > Infringement > Exclusive RightsPatent Law > Infringement > Defenses
[HN24] An organization on notice that it is infringing another's patent should inquire into the validity of the patent before rather than after the alleged infringing activities begin.

Patent Law > Remedies > Damages
[HN25] Multiplication of damages depends upon the degree of bad faith exhibited by the defendant.

Patent Law > Remedies > Costs & Attorney Fees
[HN26] An award of reasonable attorney's fees pursuant to *35 U.S.C.S. § 285* is appropriate where there has been a finding of willful infringement.

Patent Law > Remedies > Damages
[HN27] The Supreme Court has recently construed *35 U.S.C.S. § 284* to require that prejudgment interest ordinarily be awarded.

Patent Law > Remedies > Damages
[HN28] The standard governing the award of prejudgment interest under *35 U.S.C.S. § 284* should be consistent with Congress' overriding purpose of affording patent owners complete compensation. In light of that purpose, the Supreme Court concluded that prejudgment interest should ordinarily be awarded. In the typical case an award of prejudgment interest is necessary to ensure that the patent owner is placed in as good a position as he would have been in had the infringer entered into a reasonable royalty agreement. An award of interest from the time that the royalty payments would have been received merely serves to make the patent owner whole, since his damages consist not only of the value of the royalty payments but also of the foregone use of the money between the time of infringement and the date of the judgment.

Patent Law > Remedies > Damages
[HN29] The district court may "fix" the interest and select an award above the statutory rate, or select an award at the prime rate. Once the claimant has affirmatively demonstrated that a higher rate should be used, the district court may fix the interest or that higher rate.

COUNSEL: [**1]

Bruce M. Stargatt, Esquire, Richard H. Morse, Esquire, Young, Conaway, Stargatt & Taylor, Wilmington, Delaware, John O. Tramontine, Esquire, Eric C. Woglom, Esquire, Jesse J. Jenner, Esquire, Richard M. Barnes, Esquire, Douglas J. Gilbert, Esquire, Fish & Neave, New York, New York, for Plaintiff.

Paul E. Crawford, Esquire, Connolly, Bove, Lodge & Hutz, Wilmington, Delaware, John D. Gould, Esquire, Douglas J. Williams, Esquire, Mark J. DiPietro, Esquire, Merchant, Gould, Smith, Edell, Welter & Schmidt, Minneapolis, Minnesota, for Defendant.

JUDGES:

Walter K. Stapleton, Circuit Judge. n1

n1 Honorable Walter K. Stapleton, United States Circuit Judge for the Third Circuit, sitting by designation.

OPINIONBY:

STAPLETON

OPINION:

[*1370] STAPLETON, Circuit Judge:

This is a patent infringement action brought by plaintiff Schering Corporation against defendant Precision-Cosmet Co., Inc. ("P-C"). On March 11, 1985, a jury returned a general verdict for Schering in the amount of $1,263,482, along with answers to a number of interrogatories. Currently before the Court are motions by both parties. P-C has moved for Judgment Notwithstanding the Verdict ("JNOV") and, in the alternative, for a [**2] new trial. Schering has moved for an award of prejudgment interest, increased damages, and reasonable attorney's fees.

I. MOTION FOR JNOV

[HN1] The moving party is entitled to a JNOV when the Court is convinced:

> [*1371] (1) that reasonable persons could not in light of . . . [the] evidence have found the facts necessary to support the jury's verdict; *or* (2) that the facts properly found cannot in law support that verdict. If, on the other hand, the court is convinced that reasonable persons could have found in light of . . . [the] evidence the facts necessary to support in law the jury's verdict, denial of the motion for JNOV is required.

Weinar v. Rollform, Inc., 744 F.2d 797, 805 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co., 722 F.2d 1542 (Fed. Cir. 1983)).*

[HN2] The Federal Circuit has also set forth guidelines that a court must follow in considering a motion for JNOV. Under these guidelines, a court must:

> (1) consider all the evidence; (2) in a light most favorable to the non-mover; (3) drawing reasonable inferences favorable to the non-mover; (4) without determining credibility of witnesses, and (5) without substituting its choice [**3] for that of the jury between conflicting elements in the evidence.

Connell v. Sears, 722 F.2d at 1546. Further, [HN3] where as here the issue raised is validity, "the true question is whether [defendant], which bore the burden, *35 U.S.C. § 282,* submitted such evidence as would preclude a reasonable jury from reaching a verdict of validity." *Weinar v. Rollform, 744 F.2d at 805.* In this regard, it is well to note that the question presented by a motion for JNOV is *not* whether the district court would have found the invention obvious as though there had been no trial before a jury. *Id.* Rather, the question is whether the jury's verdict that the Schering patent is valid (i.e. has not been proved invalid) is supported by substantial evidence. *Id.* (citing *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp., 739 F.2d 604 (Fed. Cir. 1984)).*

Notwithstanding these principles, P-C argues that the trial court may review the issue of validity de novo. In so doing, P-C relies upon the Federal Circuit's recent statement in *E.W.P. Corp. v. Reliance Universal, Inc., 755 F.2d 898, 905 (Fed. Cir. 1985),* that validity "is a question of law and that question is freely [**4] reviewable by this court." *E.W.P. Corp.*, however, was not tried before a jury. In *Connell v. Sears*, the court explained that [HN4] though obviousness is indeed a question of law, it is an issue that may properly be submitted to a jury, in the same manner that other legal questions, such as negligence, are regularly submitted to juries in personal injury cases. *722 F.2d at 1547; Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1514-15 (Fed. Cir. 1984).* Thus, though P-C is clearly correct that obviousness is a question of law, it is equally clear that when faced with a motion for JNOV concerning a verdict of validity, consideration of that motion by the trial court is limited by the standard of

review and guidelines set forth in *Connell v. Sears* and *Weinar v. Rollform.*

A. *The Obviousness Issue*

The parties agree, for purposes of the motion for JNOV and a new trial, that the claimed invention is a gas permeable hard contact lens made principally of tertiary butyl styrene ("TBS"). P-C contends that such an invention would have been obvious to one with ordinary skill in the art in light of seven items of prior art, only one of which was before the Patent Examiner: [**5] (1) the Fatt article (DX-212AG); (2) Larke & Tighe U.K. Patent No. 1,394,056 (DX-212M); (3) Gaiser U.S. Patent No. *2,674,743* (DX-212B); (4) the Salame article (DX-212H); (5) Lundberg U.S. Patent No. *4,057,598* (DX-212C); (6) the Dow brochures (DX-212AH, DX-212AI), and (7) Larke U.K. Patent No. 1,395,501 (DX-212N).

Defendants contend that the above prior art paved a clear path to the inventor's decision to substitute the higher alkyl styrenes, including TBS, in a hard contact lens formulation, in order to provide improved gas permeability.

I conclude, however, that there is substantial evidence in the record supporting the conclusion that the subject matter of the invention of the Schering patent [*1372] taken as a whole would not have been obvious at the time the invention was made to a person of ordinary skill in the art.

A principal contention made by P-C with respect to the question of obviousness is that the high gas permeability of a TBS lens would be predicted in 1977 on the theory that the addition of bulkier side groups to a polymer creates a more "open structure" (lower density) for the passage of oxygen. P-C presented the testimony of Dr. Salame for purposes of explicating [**6] this theory. Both of Schering's experts, however, expressly opined that the higher permeability of TBS would not have been predictable and provided reasons for their opinions. Dr. Hoehn expressly stated that the permeability of TBS was not predictable. (Tr. 1620). He explained that, contrary to Dr. Salame's theory, permeability of a material is not a property of the polymer; it is instead a property of the article made from the polymer. (Tr. 1618). According to Dr. Hoehn, predicting permeability with any degree of success depends on whether one has studied the article made from the polymer. *Id.*

Dr. Fatt testified that he would not be able to predict increased permeability of a polymer merely on the basis that bulkier side groups were added. (Tr. 343). Dr. Fatt opined that gas permeability was predicted upon two components -- the speed at which the molecule traveled through the plastic and the solubility of the gas in the plastic -- and that these components could offset one another with the result that addition of a bulkier group would not necessarily lead to increased permeability. (Tr. 343). He also indicated that the lower density of a polymer did not always lead to increased [**7] permeability. (Tr. 342).

Dr. Fatt further testified that the increased permeability of ethyl, isopropyl and tertiary butyl styrene over stryene and methyl styrene was unexpected. (Tr. 270-71). Mr. Deichert of Bausch & Lomb also acknowledged that the permeability of TBS was "surprising and unexpected". (Tr. 1093).

P-C contends that the Larke & Tighe patent (DX-212M) teaches one skilled in the art that the addition of bulkier side groups, by providing more open space, will improve oxygen permeability. P-C's reference here is not to any teaching concerning the compositions claimed in the Schering patent but, rather, to the following language of the Larke & Tighe patent:

> Although the invention is not limited to any particular theory, it is believed that the bulky side groups attached to the polymer chain disrupt the chain symmetry and regularity of the polymer giving a more open structure having increased gas permeability.

Given the contrary testimony of Dr. Fatt and Dr. Hoehn as to the understanding of those working in the art at the relevant time, the jury was not bound to conclude that the artisan of ordinary skill would take this theoretical speculation at face value. Testimony [**8] to the contrary by Drs. Hoehn and Fatt represented substantial evidence that increased permeability was not predictable.

Dr. Fatt further testified that the use of TBS in a hard contact lens would not have been obvious to him from the Lundberg patent (DX-212C). He explained that the patent disclosed TBS as one of 25 to 30 monomers for the hydrophobic block of a copolymer and that one of the 25 possible uses for the copolymer was a soft, not *hard*, contact lens. He indicated that there was no mention of gas permeability in Lundberg. (Tr. 279-293). He explained that out of the many possible combinations of uses with different monomers, disclosed by Lundberg, it would not have been obvious to pick out the use of TBS in a soft lens, let alone in a hard one. (Tr. 292).

As to the Gaiser patent (DX-212B), Dr. Fatt indicated that neither TBS nor any other alkyl styrene claimed in the Schering patent is mentioned in Gaiser. (Tr. 297). Moreover, both Drs. Fatt and Salame testified that the substituted styrenes referred to by Gaiser constituted a class of more than one hundred compounds.

(Fatt Tr. 297-98; Salame Tr. 1271-72). Most significantly, [*1373] Fatt testified that Gaiser did [**9] not mention anything with respect to the improved gas permeability that resulted from the use of certain substituted styrenes. (Tr. 297).

While Dr. Salame testified that the increased permeability of TBS would have been obvious, [HN5] the jury was entitled to reject his testimony if they did not find it credible. And it is not the province of this Court to weigh the credibility of Salame's testimony against the testimonies of Hoehn and Fatt. *Connell v. Sears, 722 F.2d at 1546-47.*

The question here is whether P-C, in light of its burden to prove invalidity by clear and convincing evidence, submitted such evidence as would preclude a reasonable jury from reaching a verdict of validity. I conclude that it did not and that the jury's conclusion on obviousness was supported by substantial evidence.

B. *Anticipation*

P-C argues that the Gaiser patent, which teaches that contact lenses can be made of styrene or substituted styrenes, anticipates a number of the asserted claims of the Schering patent. P-C points to the testimony of Dr. Fatt and Dr. Loshaek. Dr. Fatt testified that he would have understood the reference to substituted styrenes in the Gaiser patent to mean divinyl benzene. [**10] (Tr. 295-296). He also indicated that a contact lens of divinyl benzene, having a substantial amount of ethyl styrene as an impurity, would come within the language of claim 1 of the patent-in-suit. Dr. Loshaek testified that the term "substituted styrenes" could mean the styrenes he had been testifying about, including TBS. (Tr. 1460-61).

Dr. Fatt also testified, however, that neither TBS, isopropyl styrene, ethyl styrene, nor any other substituted styrene are mentioned in the Gaiser patent. (Fatt 295-297). Dr. Fatt also stated that Gaiser did not mention gas permeability with respect to substituted styrenes. (Tr. 297). In addition, both Drs. Fatt and Salame testified that the class of substituted styrenes includes more than one hundred compounds. (Fatt Tr. 297-298; Salame Tr. 1271-72).

As recently stated by the Federal Circuit:

> [HN6] A party asserting that a patent claim is anticipated under *35 U.S.C. 102* must demonstrate . . . identity of invention. In cases like this, identity of invention is a question of fact, and one who seeks such a finding must show that each element of the claim in issue is found, either expressly described or under principles of inherency, in a single [**11] prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice. . . . (citations omitted).

Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771-72 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026, 104 S. Ct. 1284, 79 L. Ed. 2d 687 (1984).

[HN7] The general rule is that a prior genus does not anticipate a later species. I Chisum, *Patents* § 3.02[2] (1985); *see In re Ruschig, 52 C.C.P.A. 1238, 343 F.2d 965 (C.C.P.A. 1965).* If, however, it is possible to derive a class of compounds of lesser scope than the genus disclosed in a prior art reference on the basis of preferences ascertainable from the remainder of the reference, anticipation may be found. *E.g., Application of Schaumann, 572 F.2d 312, 316 (C.C.P.A. 1978); In re Petering, 49 C.C.P.A. 993, 301 F.2d 676, 681 (C.C.P.A. 1962).* The anticipating reference must contain within its four corners a sufficient description to enable one to practice the invention without experimentation or inventive skill. *Philips Elec. & Pharmaceutical Indus. Corp. v. Thermal & Elec. Indus., Inc., 450 F.2d 1164, 1169 (2d Cir. 1971); Dewey & Almy Chem. Co. v. Mimex* [**12] *Co., 124 F.2d 986, 990 (2d Cir. 1942);* I Chisum, *Patents* § 3.04[1][6] (1985). *See CBS v. Sylvania Electric Prod., Inc., 415 F.2d 719, 725 (1st Cir. 1969)* (test is whether the prior art reference "describes the invention with sufficient clarity and specificity so that one skilled in the art may practice the invention without assistance from the patent claimed to have been anticipated.")

[*1374] Based on these principles, I conclude that there was substantial evidence in the present case from which a reasonable jury could conclude that Gaiser did not anticipate the various claims of the Schering patent. Indeed, given the text of the Gaiser patent and the undisputed evidence with respect to the number of compounds coming within the class of substituted styrenes, it is difficult to understand how the jury could have concluded otherwise. Gaiser does not mention any particular substituted styrene, makes no references to the permeability of specific substituted styrenes, and provides no basis whatever for preferring any sub-group of substitute styrenes over other substituted styrenes for use in making contact lenses. Given the fact that substituted styrenes comprise a [**13] class in excess of one hundred compounds, it seems clear that the elements of the claimed invention, namely TBS, were not adequately described by Gaiser for purposes of identification; and that one of ordinary skill in the art would have had to engage in extensive experimentation to get from Gaiser to the Schering invention.

In re Petering and *In re Schaumann*, cases relied on by P-C, both involved situations where a reference disclosing a broader group of compounds was narrowed to a small, definite and limited class of compounds by preferences expressed in the remainder of the disclosure. In the present case, there was evidence indicating that Gaiser would not have pointed one toward a more limited class of substituted styrenes, such as, for example, the alkyl styrenes disclosed by the patent-in-suit.

C. *New Use For Old Substance Issue*

P-C argues that as a matter of law claims 1, 15, 18, 21, 25 and 27 are invalid as reading on a homopolymer of TBS, which is admittedly an old composition. P-C predicates its argument upon the well-established doctrine that [HN8] a new use for an old substance is not patentable. *In re Thuau, 30 C.C.P.A. 979, 135 F.2d 344 (C.C.P.A. 1943).* [**14] Thus, P-C argues that the terms "contact lens" and "buttons" appearing in the preambles of the various challenged claims merely describe a new use for TBS.

I conclude, however, that rather than merely claiming a new use for TBS, the Schering patent discloses a new composition *made* from TBS, i.e., a hard gas permeable contact lens or button. In *Thuau*, the applicant attempted to claim a compound that he had failed to "change in any way." *Id.* at 347. Here, the Schering patent discloses more than the mere chemical composition TBS; it claims contact lenses that have been cut and shaped from the raw compound itself. Such a modification is legally significant and prevents the challenged claims from falling under the doctrine of *In re Thuau*.

[HN9] "The rule that no product patent may issue for discovery of a new use for an old product or process is tempered by the 'doctrine of slight changes.'" Chisum, I *Patents* § 1.03[8] [b] at 1-171 (1985). The doctrine of slight changes extends to the area of chemical compounds. *Id.* at 1-174. That the modification of an old compound into a new patentable one may indeed be slight is illustrated by *Application of Wiggins, 55* [**15] *C.C.P.A. 1356, 397 F.2d 356 (C.C.P.A. 1968).*

Wiggins sought to patent a compound (referred to by the court as 0[2]) because of its analgesic and pain relieving activity in humans. One of Wiggins' claims rejected by the examiner and Board of Appeals prescribed a dosage of 0[2] from "about 10 milligrams to about 1000 milligrams." *Id.* at 358. The prior art consisted of an article by Wolf describing the exact same compound and its use in protecting mice from x-ray radiation. Wolf did not suggest the use for 0[2] discovered by Wiggins, nor did Wolf suggest administering 0[2] in the 10 to 1000 milligram range disclosed by Wiggins. The Board of Appeals rejected the application on the ground that Wiggins had "discovered a new use for an *old* composition." *Id.* at 359 n. 5 (emphasis supplied by Board). The court disagreed, finding that Wiggins had discovered a new composition since the amounts of 0[2] employed by Wiggins in his composition were different from [*1375] the amounts that Wolf had administered in his experiments. *Id.* at 359-60.

In light of *Wiggins*, wherein [HN10] a mere change in the *amount* of a compound was deemed sufficient to change an old composition [**16] into a new one, it would appear to follow that the transformation of TBS into a contact lens involves the creation of a new composition.

In arguing to the contrary, defendants rely heavily upon *Application of Benner, 36 C.C.P.A. 1081, 174 F.2d 938 (C.C.P.A. 1949).* In that case, the applicant argued that he had changed the shape of the compound at issue. The court rejected this argument because the applicant had failed to describe the purported change in shape in the claims of the patent. *Id.* at 942-43. Moreover, the court refused to recognize the introductory phrases of the challenged claims -- which recited a "ball mill lining element" -- for purposes of showing that the compound described in the claims had been shaped into a particular article, i.e., a new composition. P-C similarly argues that the challenged claims of the Schering patent, as distinct from their preambles, merely describe TBS, and that Schering cannot use the preambles, which describe contact lenses and buttons, to further limit what is already defined by the claims themselves.

After *Benner*, [HN11] the Court of Claims and Patent Appeals in *Kropa v. Robie, 38 C.C.P.A. 858, 187 F.2d 150 (C.C.P.A. 1951),* [**17] set down guidelines for determining when the introductory phrase of a claim would be permitted to limit the claim itself. The court indicated that the preamble would be permitted to limit a claim where it "was deemed essential to point out the invention defined by the claim or count," that is, where "the preamble was considered necessary to give life, meaning and vitality to the claims or counts." *Id.* at 152. The court performed an exhaustive analysis of prior precedent and found *inter alia*:

> The preamble is a limitation where it specifies an article or composition in which there inheres a field of specific use, and the constituents of the article which are recited in the portion of the count following the preamble are old compounds not theretofore known to be useful in such an article.

Id. at 159. [HN12] The Court of Appeals for the Federal Circuit has continued to look to the preamble when "necessary to give meaning to the claim and properly define the invention." *Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 896 (Fed. Cir. 1984), cert. denied, 469 U.S. 857, 53 U.S.L.W. 3239, 83 L. Ed. 2d 120, 105 S. Ct. 187 (1984).*

In the present case, the words [**18] "contact lens" and "button" are essential to point out the invention defined by the claims. It is only by reference to the introductory phrase of the challenged claims that it can be known that the subject matter defined by the claims is comprised as a contact lens or as a button adapted to be formed into a lens. In so holding, I note that [HN13] "claims should be so construed, if possible, as to sustain their validity." *ACS Hosp. Systems, Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir. 1984).*

D. *Structural Similarity*

P-C contends that a hard contact lens of TBS was obvious because TBS is an "isomeric homolog" of the prior art styrene or methyl styrene hard contact lenses.

[HN14] While it is true that close structural similarity between prior art compounds and those that are claimed may be an indicia of obviousness, the subject matter of the invention as a whole may be non-obvious if the claimed compound has unexpected properties. *Application of Payne, 606 F.2d 303, 314 (C.C.P.A. 1979); In re Papesch, 50 C.C.P.A. 1084, 315 F.2d 381 (C.C.P.A. 1963).*

In the present case, the jury was presented with substantial evidence upon which it could reasonably have concluded that [**19] a lens of TBS had such unexpected properties as to rebut any inference that might be drawn from structural similarity. Dr. Fatt, for example, testified that the two alkyl styrenes preferred by the Schering patent, TBS and isopropyl styrene, as well as ethyl styrene, all demonstrated unexpected increases in gas permeability over [*1376] the prior art styrene and methyl styrene. (Fatt Tr. 270-71).

II. MOTION FOR A NEW TRIAL

P-C moves in the alternative for a new trial on the grounds that (1) the verdict with respect to a number of issues is against the weight of the evidence; (2) the damages are excessive; and (3) errors in certain of the jury instructions prejudiced defendant's case.

[HN15] A motion for a new trial differs from a motion for JNOV in that:

> A motion for a directed verdict or for judgment n.o.v. raises the legal sufficiency of the evidence, and is to be sharply distinguished from a motion for a new trial on the ground that the verdict is against the weight of the evidence. The latter motion is addressed to the sound discretion of the trial court, which may set aside the verdict as contrary to the preponderance of the evidence although a directed verdict or judgment [**20] n.o.v. is not justified (footnote omitted).

6A J. Moore, *Moore's Federal Practice* § 59.08(5) (2d ed. 1984) (hereinafter Moore, *supra*). [HN16] The standard of review in considering a motion for a new trial is most often formulated in one of three ways. Thus, a new trial will be granted if the verdict is against the *clear* weight of the evidence, *Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 626 (Fed. Cir. 1985);* 6A Moore, *supra* § 59.08(5) (emphasis added), or if the court is convinced the jury has reached a "seriously erroneous result," *Herman v. Hess Oil Virgin Islands Corp., 379 F. Supp. 1268, 1271 (D.V.I. 1974), aff'd, 524 F.2d 767 (3d Cir. 1975),* 6A Moore, *supra*, § 59.08(5), or if there has been a miscarriage of justice. *Parsons v. Doctors For Emergency Services, 81 F.R.D. 660, 662 (D. Del. 1979);* Moore, *supra* § 59.08(5).

A. *Infringement By Saturn II Lens*

P-C contends that the jury's finding of infringement of the Schering patent by the Saturn II lens is against the weight of the evidence. P-C argues that the Saturn II, because of its soft skirt, is fundamentally different from the hard contact lens claimed by [**21] the Schering patent and could not have infringed the Schering patent either literally or under the doctrine of equivalents. I conclude, however, that the clear weight of the evidence does not warrant overturning the jury's finding of infringement with respect to the Saturn II.

P-C admits that the Saturn II lens is characterized by a hard center. Dr. Fatt testified that the portion of the Saturn lens that its wearer looks through is hard, and that, as far as vision is concerned, the Saturn II is a hard contact lens. (Fatt Tr. 385). P-C admits (Def. Br. 36) that the hard portion of the Saturn II functions to correct astigmatism and there was testimony during trial that one of the advantages of the hard lens over the soft is that the hard lens corrects astigmatism.

Since the asserted claims of the Schering patent are not closed, the addition of the soft skirt to the hard center of Saturn II did not preclude a finding of literal infringement by the jury. In addition, the jury was entitled to conclude that Saturn II infringed under the doctrine of equivalents -- especially in light of Dr. Fatt's testimony.

I am not persuaded that the verdict of infringement was clearly not based upon [**22] a preponderance of

the evidence, or that there has been a miscarriage of justice with respect to this issue.

B. *The Question Of Validity*

P-C submits that for the same reasons it is entitled to a JNOV on the issues of obviousness and anticipation, it is alternatively entitled to a new trial on those issues on the ground that the jury's verdict is against the weight of the evidence. Having already discussed much of the relevant testimony and evidence with respect to this matter, I need not repeat it here.

Suffice it to say that I am unable to conclude that the jury's determination respecting validity was contrary to the clear weight of the evidence.

[*1377] C. *Damages*

P-C contends that Schering failed to satisfy its burden of showing what a reasonable royalty would be, and that the jury's award is excessive and against the weight of the evidence.

Schering introduced evidence as to what would be a reasonable royalty for P-C's infringement through the testimony of Dudley Smith, an expert on patent licensing. Basically, Mr. Smith concluded that after a hypothetical licensing negotiation, the parties would have agreed to a 50/50 split of profits which he translated into [**23] a royalty based upon 30% of the gross projected sales prices for all lenses made by P-C. P-C did not challenge Mr. Smith's credentials or experience at trial and he is clearly a well qualified expert on licensing. Notably, P-C did not offer the expert testimony of any licensing witness of its own.

Mr. Smith provided extensive testimony explaining how he arrived at his recommended reasonable royalty. He explained that the procedure for determining a reasonable royalty is to assume a hypothetical negotiation between a willing licensor and willing licensee who are attempting to agree on a reasonable royalty rate for a license under the patent-in-suit. Smith constructed the hypothetical negotiation by using what he considered a generally recognized royalty rate for patent licenses and then considering the effect of numerous factors that might increase or decrease the initially chosen rate. Smith evaluated the effect of approximately seventeen factors in forming his opinion as to an appropriate royalty. (Tr. 584-618).

Defendant argues essentially that Smith's opinion is unsupportable when viewed against the evidence relating to (1) other licenses in the contact lens field; (2) established [**24] royalty rates in the optical and chemical industries; and (3) other gas permeable lenses on the market.

P-C's first argument is that it produced uncontroverted evidence of royalty rates currently in place in the contact lens industry, i.e., the Erickson agreement (DX-256), n2 which provides a royalty rate of 5% on net sales, and the Bausch & Lomb agreement, which provides a 10% royalty of net sales on the sale of Saturn II lenses by B & L (5% to P-C and 5% to Erickson). (DX-135). P-C further points to a number of statements by Smith that P-C claims undermine his opinion concerning the royalty that ought to apply to the present case. According to P-C, Smith allegedly agreed with a statement from the Finnegan article that most royalty rates are 5 to 6% based on net sales, he admitted that seldom do licensees use profit as a basis for calculating royalties, and also agreed with a statement that in the optics and chemical fields royalties are based upon net sales, not gross profits, and that royalties range from 2% to 5%.

n2 This agreement provided for the transfer to P-C of the Saturn lens technology from Erikson.

[**25]

With respect to the Erickson agreement, upon which P-C particularly relies in pressing its motion for a new trial on the issue of damages, Smith testified that it was not "analogous" to the agreement that would have been hypothetically negotiated between Schering and P-C. Smith indicated that under the *Georgia Pacific* analysis the patent at issue is assumed valid and infringed during negotiations. The consequence of this assumption is that the royalty tends to increase. (Tr. 587, 687). Smith distinguished Erickson on the ground that it did not involve a patent presumed to be "invalid and infringed." (Tr. 687).

Moreover, while the Erickson agreement licensed P-C under Erickson's patent, it did so at a time (1977) when the Saturn lens had a PMMA center and was years away from being ready for submission to the FDA with a TBS center (which P-C did not do until 1984), and thus was far less valuable to P-C than a license in July 1981 under Schering's patent. In addition, the royalty under the Erickson agreement was accompanied by a substantial fixed payment (DTX-256), and there is no evidence that Erickson was ever a gas permeable hard contact lens supplier so that P-C would be a competitor [**26] of Erickson. Smith [*1378] indicated that each of these factors would have a substantial impact on the royalty rate.

P-C's claims that Smith agreed with actual statements from the Finnegan article relating to the rate of typical industry royalties and the rate of royalties in

the field of optics and chemicals are belied by the record. Smith testified that he could *not* agree with the proposition that common industry royalty rates were 5-6% of net sales for two reasons. First, he had not seen the survey on which the statement was based, and second he explained that the statement of typical rates does not show whether a patent license is involved "let alone a patent that had been held valid and infringed." (Tr. 272). Smith was also unable to agree with the statement concerning typical royalty rates in the chemical and optics industries. He explained that the statement was too broad, and that he would need to know what type of license was being referred to, since royalty rates varied according to the nature of the license. (Tr. 677-78).

Moreover, there was testimony by Smith relating to the Finnegan article that actually supported his calculations of a reasonable royalty. He [**27] indicated that the 5% royalty rates based on net sales referred to in the Finnegan article related to "commercial cases where . . . none of the patents have been held valid and infringed." He pointed out on the other hand that Finnegan described a case where "the Court awarded a reasonable royalty which equalled forty-eight percent of the patent infringer's profits." (Tr. 714).

Smith also testified at several points explaining why he calculated his royalty based on projected gross sales of all manufactured lenses rather than net sale of units sold as advocated by P-C. (Tr. 706-709; 1805-1807).

Finally, P-C argues that the rate recommended by Smith was unjustifiably high since the Airlens did not constitute an extraordinarily unique product giving a competitive advantage to the licensee. This factor was, of course, one of many that the jury was free to consider in determining the appropriate royalty. But even if, as P-C contends, the value of the Airlens to a hypothetical licensee was reduced in 1981 because the lens market was occupied by numerous competitors, I am not persuaded that this factor, alone or in combination with any others cited by P-C, constituted evidence that clearly [**28] rebutted Smith's testimony.

Thus, while [HN17] the burden was on Schering to prove damages by a "reasonable probability", *Gyromat Corp. v. Champion Spark Plug Co., 735 F.2d 549, 555 (Fed. Cir. 1984),* I conclude from the foregoing that Schering successfully and persuasively carried this burden. Virtually all of the arguments that P-C now raises with respect to the evidence were addressed and rebutted by Smith. The jury was free to credit his testimony and it is not surprising that it did so given the fact that no expert testimony was offered to contradict his views. n3

n3 *See Hanson v. Alpine Valley Ski Area Inc., 718 F.2d 1075, 1079 (Fed. Cir. 1983)* (discussing the failure of defendant to counter plaintiff's expert license witness with one of its own).

D. *Jury Instructions*

In support of its motion for a new trial, P-C asserts that there were a number of errors of omission and commission in the instructions given to the jury. I remain of the view that the jury was adequately and correctly instructed regarding [**29] the applicable law and further conclude that, in the one area open to reasonable debate, any error that may have crept into the charge would not warrant a new trial.

The parties are in agreement as to [HN18] the standard of review of jury instructions on a motion for a new trial:

> Instructions must be viewed in their entirety. A new trial is permissible when it is clear that error in the instructions as a whole was such as to have misled the jury.

Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1518 (Fed. Cir. 1984). In addition, the error must prejudice the defendant's [*1379] case. *Shatterproof Glass, 758 F.2d at 627.*

1. "*Likely To Carry Burden*"

I declined to give the following instruction requested by P-C:

> If you find that the additional prior art relied on by defendants is more pertinent than the prior art referred to by the Patent Office during the consideration of the application for the Schering patent, then defendants are more likely to carry their burden of proof that the patent is invalid.

This requested instruction takes a comment of the Federal Circuit regarding what juries are likely to do in certain situations and attempts [**30] to convert it into a proposition of law. In my judgment, it would have been more likely to confuse the jury than to help it understand the applicable law.

In addition to being given an explanation of the patent system and what happens in the Patent Office, the jury was correctly instructed that it was required to determine, with respect to each claim, whether the evidence as a whole showed clearly and convincingly

that the subject matter of the invention would have been obvious to one of ordinary skill in the art given the prior art. The vast majority of the evidence tendered at trial was relevant to this issue. One piece of such evidence was that certain of defendant's prior art references were not before the Patent Office when it decided that the statutory requirement of nonobviousness had been met. While P-C chose not to do so, it was free to stress this particular fact to the jury in closing argument. It was not entitled, however, to have the judge single this fact out and tell the members of the jury that it meant that P-C was "more likely" to have carried its burden of proving obviousness. The relevance and importance in any particular case of evidence tending to show that [**31] some prior art references were not before the PTO will depend upon the jury's view of the other evidence bearing on the obviousness issue.

2. *Presumed Knowledge*

P-C complains that the Court failed to charge the jury regarding a presumption that "a hypothetical ordinary person skilled in the art has knowledge of all the art relied on at trial even if the patentees were actually unaware of that art." One problem with this contention is that it does not appear that P-C actually requested an instruction to this effect.

Defendant's "Request For Instruction 19A" requested the following: "You must presume the inventors were aware of all the art, whether or not they were in fact aware of it at that time." In a letter to the Court dated March 7, 1985, P-C requested a slightly different construction: "You must presume that the inventors were aware of all of the relevant art which existed at the time they made the invention, irrespective of whether they personally knew of it." [HN19] The presumption that the *inventor* has knowledge of all the art has been rejected by the Court of Appeals for the Federal Circuit. *Kimberly-Clark v. Johnson & Johnson, 745 F.2d 1437, 1454 (Fed. Cir. 1984)* [**32] ("We hereby declare the presumption that the inventor has knowledge of all material prior art to be dead.") There can, therefore, be no error in this Court's failure to adopt the above two requested instructions.

Second, at the prayer conference [HN20] P-C failed to make any request with regard to knowledge of the ordinary person skilled in the art. Under F.R. Civ. P. 51, P-C has waived any objection based on that omitted instruction.

Finally, even if the instruction had been properly requested and improperly denied, I would be unable to conclude that the error was such as to mislead the jury and prejudice the defendant. P-C is specifically concerned about Salame's Permachor System, since there was testimony from some of Schering's witnesses that persons in the art may not have been aware of that system. (Tr. 176-77, 1613). However, the jury was specifically instructed that Salame's Permachor system was part of the "stipulated or agreed upon prior art." [*1380] (Charge to the Jury, p. 16). The jury was further instructed that, on the issues of obviousness and anticipation, they were to "consider each patent or publication which has been agreed to be prior art." (Charge to the Jury, [**33] p. 25). Finally, the Court defined prior art for the jury as "the knowledge that was previously available to the public" (*id.* at 15) -- not art available to only certain individuals. n4

n4 The Court had previously instructed the jury at the outset of the trial as follows:

> So when we ask ourselves whether the invention described in the patent is new and whether it was obvious, given what had been learned earlier by others, we compare the patent with the prior art, we compare the patent with the pre-existing patents and publications in the same area that reflect what others had learned and discovered before.
>
> The prior art is what was previously available to the public and those practicing this art, and this is what is important. It does not matter whether or not it is shown that the inventor of a patent knew about or received aid from the prior art and what others had discovered.
>
> In order to have a valid patent, somebody has to be able to show that they added something of value to what was previously available to the public.

[**34]

Based on the above, I am confident that the jury was not misled as to the scope and content of the prior art or as to their duty to compare each claim of the patent-in-suit with all of P-C's prior art references.

3. *Old Composition For New Use*

In addition to claiming as a matter of law that six claims of the Schering patent are invalid because they merely disclose a new use for an old compound, *see*

section I.C., *supra*, P-C also contends that it was entitled to an instruction submitting this defense to the jury.

I have already concluded, however, that as a matter of law the Schering claims disclose a new composition. Therefore, P-C was not entitled to an instruction submitting this defense to the jury.

4. *Deichert's Work*

In support of its motion for a new trial, P-C complains of the instruction of the Court regarding claims 18, 27 and 29 of the Schering patent and the issues of whether they were anticipated by Mr. Deichert's work at Bausch & Lomb during August and September of 1977. In support of this contention, P-C relies upon the assertion that "an inventor need only appreciate the *existence* of the subject matter of his invention, but need not fully appreciate [**35] all of the functions or advantages that make it patentable." I do not disagree with this proposition; I do not think it applicable, however, to the issues of whether Deichert's work anticipates claims 18, 27 and 29.

The subject matter of claims 18, 27 and 29 is "an optically clear, non-hydrophilic contact lens" (or a "button adapted to machine" such a lens) having "a gas permeability constant of at least about 10x10-11" and being made of a polymer produced by polymerizing 70% to 100% TBS monomer, 0% to 10% "compatible cross-linking monomer" and 0% to 20% "compatible plasticizer." n5 While I acknowledge, in retrospect, that the matter is not free from doubt, I charged as I did with respect to these claims because, on the record before me, I regarded the presence of a DK value of at least 10 as well as the presence of at least 70% TBS to be part of the definition of the subject matter of these claims and not an inherent characteristic of an invention defined by the other portions of the claims. From this perspective, in order to find the inventions of these claims anticipated by Deichert, the jury would have to conclude not only that Deichert made a lens coming within the scope of the [**36] claims, but also that he appreciated that he had done so. This would include an appreciation that his 70% plus TBS lens had a DK value in excess of 10. This was significant because there was evidence that Deichert had never tested his lens for gas permeability.

> n5 As is clear from the wording of the claims, the percentage of TBS and cross-linking monomer are based on the total weight of the polymer and the percentage of plasticizer is based on the total weight of the polymer and plasticizer.

[*1381] The charge as given was intended to comport with the teachings of *Silvestri v. Grant, 496 F.2d 593 (C.C.P.A. 1974)* and *Knorr v. Pearson, 671 F.2d 1368 (C.C.P.A. 1982)*. If the gas permeability constant of 10x10-11 be regarded as an inherent characteristic of the invention otherwise defined in claims 18, 27 and 29 and these cases are to be distinguished on that basis, it still would not follow, however, that P-C is entitled to a new trial with respect to these claims. I say this because if the jury found, [**37] as it did, that P-C had not carried its burden of proving that Deichert's work anticipated the broader subject matter of the other claims-in-suit, it follows, *a fortiori*, that it did not carry its burden with respect to claim 18, 27 and 29. In this connection, it seems to me that the jury's finding of no anticipation of the other claims strongly suggests, and perhaps requires, a finding that the subject matter of the claims of the Schering patent are limited to hard contact lenses and that Deichert was found by the jury to have worked solely with soft contact lenses.

5. *Infringement*

P-C's final objection to the Court's charge is that it was erroneous to permit the jury to consider the performance characteristics of Schering AIRlens.

The Court's charge stated that Schering had the burden of proving that the accused lenses and buttons infringe the claims of the Schering patent. (Tr. 1901). The Court further instructed the jury at least four times that they should determine infringement by comparing the claims with the accused product. (Tr. 1896, 1901, 1902 and 1904).

With regard to the doctrine of equivalents, the Court instructed the jury:

> In order for the doctrine [**38] of equivalents to apply, however, each element of the claimed invention or its substantial equivalent must be found in the accused product. And the claimed invention and the accused product must perform substantially the same function in substantially the same way to yield substantially the same result.
>
> * * * *
>
> Now, as I have already explained to you, the test of infringement is whether the claims of the patent cover the accused device so that the accused products are to be compared with the claims of the Schering patent and not with the plaintiff's product, the AIRlens.
>
> However, if you reach this issue of whether the accused product and the

> claimed invention perform substantially the same function in substantially the same way to yield substantially the same result, and if you believe that the AIRlens, the plaintiff's product, comes within the scope of the claims of the patent, you may consider the evidence of Schering which compared the performance characteristics of the Airlens with those of the Opus III and Saturn II.

Id., p. 11, Tr. 1904-05.

In this context, it was not error to give the jury permission to consider the performance characteristics of the AIRlens [**39] on the issue of equivalents in the event it concluded that the AIRlens was an embodiment of the invention described in the claims of the Schering patent.

III. SCHERING'S MOTIONS

A. *Increased Damages*

In addition to its general verdict for Schering, the jury answered a number of interrogatories and found, *inter alia*, that P-C had willfully infringed each of the asserted patent claims. Schering now moves for an award of increased damages pursuant to *35 U.S.C. § 284.*

In *Underwater Devices, Inc. v. Morrison-Knudson Co., 717 F.2d 1380, 1389-90 (Fed. Cir. 1983),* the court upheld a treble damage award based on a finding of willful infringement and stated:

> [HN21] Where, as here, a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing. Such an affirmative duty [*1382] includes, *inter alia*, the duty to seek and obtain competent legal advice from counsel *before* the initiation of any possible infringing activity. (Citations omitted).

More recently, the Federal Circuit has recognized that [HN22] while counsel's opinion with respect to a patent is evidence of [**40] good faith, it is not dispositive, and it is necessary to look at the totality of circumstances presented by a case in determining whether infringement is willful. *Central Soya Co., Inc. v. Geo. A. Hormel & Co., 723 F.2d 1573, 1577 (Fed. Cir. 1983).* The Federal Circuit has also indicated that "willfulness may include a determination that the infringer had no reasonable basis for believing it had a right to do the acts." *Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1548 (Fed. Cir. 1984)* (citing *Stickle v. Heublein, Inc., 716 F.2d 1550, 1565 (Fed. Cir. 1983)).*

In the present case, the jury had before it the following evidence of willfulness. P-C knew of Schering's patent prior to P-C's application to the FDA in July 1981 for approval to sell the Opus III contact lenses. (Tr. 898-899). P-C had consulted with counsel concerning the question of infringement of the Schering patent prior to the July 1981 FDA application. (Tr. 432-435). The issue of infringement was discussed at the July 1981 meeting of Frigitronic's Board of Directors and is reflected in the following statement taken from the minutes of that meeting:

> Mr. West presented an article stating [**41] the opinion that gas permeable hard lenses are the product of the future. Our OP346[**] has the highest oxygen permeability of all lenses aside from the silicones. It can be manufactured in our present facility. However, we may be infringing a patent application.

(PTX-84, p. 4). Mr. Ralph E. Crump, President of Frigitronics, Inc., testified that he "assume[d]" that the patent application referred to in these minutes was the Wesley-Jessen (Schering) patent. (Tr. 437-39). n6 There was also evidence that in May-June 1981, P-C made a "blind inquiry" to determine whether Schering would be willing to grant a license under its patent. To conceal its identity while making this inquiry, P-C hired a lawyer from Chicago to contact Schering, so that Schering would not suspect that the call came from P-C or P-C's counsel, both of whom were located in Minneapolis. (PX-51, 52, 53; Schmidt Tr. 1700; West Tr. 1699). Finally, there was evidence that as of May 1984, P-C continued to receive advice from counsel that it was infringing the patent-in-suit. As stated in the May 15, 1984 minutes of the Board of Directors:

> Our attorneys have said we must invalidate the Schering patent in [**42] order to win this case, since otherwise we would be infringing. They say we have a 60-70% chance based on prior art. (PX-88).

n6 The parties agreed that any statement or admission made by Frigitronics would be binding on P-C as if it had been made by P-C itself (see Charge To The Jury, March 11, 1985, p. 2).

Notwithstanding this evidence that P-C knew it might be infringing Schering's patent, P-C tendered no evidence that it had obtained an opinion from competent counsel analyzing and evaluating the validity of the Schering patent.

In light of the foregoing, my views are in accordance with those of the jury respecting the issue of willful infringement. P-C was on notice from mid-1981 that it was probably infringing the Schering patent. Yet, P-C came forward with little in the way of demonstrating that it relied in good faith upon competent opinion of counsel as to the invalidity of the Schering patent. While P-C apparently had been advised by its attorneys that there was a "60-70% chance" of invalidating [**43] Schering's patent, this opinion does not satisfy the criteria for reasonable reliance spelled out in *Underwater Devices, 717 F.2d at 1390* (Memorandum [HN23] containing "only bold, conclusory, and unsupported remarks regarding validity" is inadequate). Additionally, the May 1984 Statement would appear to have come too late for purposes of demonstrating good faith. [HN24] An organization on notice that it is infringing another's patent should inquire into the [*1383] validity of the patent *before* rather than *after* the alleged infringing activities begin. *Underwater Devices, 717 F.2d at 1390* (emphasis supplied by court).

Since I am in agreement with the jury that Schering made out its case of willful infringement, I will award Schering double damages. I have decided to double the damages rather than treble them for three reasons. First, this is not a case where a successful patented product is introduced to the market and is later copied by the alleged infringer. P-C presented testimony that it had been developing its contact lenses for approximately two years before becoming aware of the Schering patent. The same testimony indicated that P-C began working with TBS without knowledge [**44] that TBS had ever been used in a contact lens. (Tr. 823-836). [HN25] "Multiplication of damages depends upon the degree of bad faith exhibited by the defendant," *Trio Process Corp. v. L. Goldstein's Sons, Inc., 638 F.2d 661, 662-63 (3d Cir. 1981),* and the fact that P-C developed its lenses independently significantly diminishes the degree of its culpability.

Second, while P-C did not satisfy its affirmative duty to obtain some reasonable basis for believing in the invalidity of the Schering patent before commencing production of its lenses, it has not litigated this case in bad faith. By the time of trial, counsel for P-C, based upon the prior art and the testimony of a highly qualified expert, Mr. Salame, had developed litigable issues with respect to validity and I am confident that P-C and its counsel believed in the merits of its defense at trial.

Finally, while wholly justified given the record before it, I believe the jury's evaluation of damages was on the high side of the permissible range.

B. *Attorney's Fees*

Schering moves for [HN26] an award of reasonable attorney's fees pursuant to *35 U.S.C. § 285.* Such an award is appropriate where, as here, there has been a finding of willful [**45] infringement. *E.g., Kori Corp. v. Wilco Marsh Buggies & Draglines, Inc., 761 F.2d 649 (Fed. Cir. 1985); Central Soya Co., Inc. v. Geo. A. Hormel & Co., 723 F.2d 1573, 1577-78 (Fed. Cir. 1983); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540 (Fed. Cir. 1984).*

C. *Prejudgment Interest*

Schering has moved pursuant to *35 U.S.C. § 284* for an award of prejudgment interest.

There can be little doubt that Schering is entitled to such an award. [HN27] The Supreme Court has recently construed *35 U.S.C. § 284* to require that prejudgment interest ordinarily be awarded:

> [HN28] The standard governing the award of prejudgment interest under § 284 should be consistent with Congress' overriding purpose of affording patent owners complete compensation. In light of that purpose, we conclude that prejudgment interest should ordinarily be awarded. In the typical case an award of prejudgment interest is necessary to ensure that the patent owner is placed in as good a position as he would have been in had the infringer entered into a reasonable royalty agreement. An award of interest from the time that the royalty payments would have been received merely serves to make the patent owner [**46] whole, since his damages consist not only of the value of the royalty payments but also of the foregone use of the money between the time of infringement and the date of the judgment. (footnote omitted)

General Motors Corp. v. Devex Corp., 461 U.S. 648, 655-56, 76 L. Ed. 2d 211, 103 S. Ct. 2058 (1983). P-C has not alleged any facts demonstrating that a prejudgment award would be inappropriate in this case.

Schering relies upon *Lam, Inc. v. Johns-Manville Corp., 718 F.2d 1056, 1066 (Fed. Cir. 1983)* for the proposition that this Court may adopt for prejudgment interest a rate above the Treasury bill rate set by *28 U.S.C. § 1961* for post-judgment, namely the prime

interest rate or the corporate [*1384] bond rate. However, the court in that case stated:

> [HN29] The district court may "fix" the interest and select an award above the statutory rate, or select an award at the prime rate. Once the claimant has *affirmatively demonstrated* that a higher rate should be used, the district court may fix the interest or that higher rate. (citations omitted).

718 F.2d at 1066 (emphasis added). In the present case, Schering offered no evidence which would support [**47] an award above the statutory rate. In *Lam, Inc. v. Johns-Manville Corp.*, the claimant "affirmatively demonstrated and the district court found that Lam borrowed money at or above the prime rate in order to continue its operations." *Id.* A comparable showing has not been made by Schering here. Accordingly, an award of prejudgment interest will be made at the Treasury bill rate as set forth in *28 U.S.C. § 1961,* compounded annually. I also endorse the method by which Schering has calculated the prejudgment interest which it seeks.

IV. CONCLUSION

P-C's motion for a JNOV or a new trial will be denied. Schering will promptly submit an amended form of final judgment which will double the damages found by the jury and will include interest from the time each reasonable royalty payment would have been made until the date of judgment. This final judgment will also award counsel fees in an amount to be hereafter agreed upon or fixed by the Court.

LEXSEE

SYMBOL TECHNOLOGIES, INC., Plaintiff-Appellee, v. OPTICON, INC., and OPTO ELECTRONICS, Defendants-Appellants

No. 90-1409

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

935 F.2d 1569; 1991 U.S. App. LEXIS 12233; 19 U.S.P.Q.2D (BNA) 1241; 33 Fed. R. Evid. Serv. (Callaghan) 1381

June 14, 1991, Decided

PRIOR HISTORY: [**1] Appealed from: U.S. District Court for the Southern District of New York; Judge Wood.

CASE SUMMARY:

PROCEDURAL POSTURE: Defendants sought review of the judgment of the U.S. District Court for the Southern District of New York, which concluded that plaintiff's patents were not proved invalid or unenforceable and found infringement.

OVERVIEW: Plaintiff sued defendants for infringement of certain patent claims. Defendants denied infringement and filed a counterclaim for declaratory judgment that patents were invalid and unenforceable. Following a non-jury trial, the district court concluded that the patents were not proved invalid or unenforceable, and found infringement. On appeal, the court held that expert opinion was admissible without the need to reveal the facts or data underlying his opinion. Because defendant failed to cross examine the witness on those issues, it could not claim error on appeal. Further, references to prior art for determining obviousness were immaterial because the considered references did not disclose or suggest the features critical to the invention's patentability. Thus, the omitted references added nothing to the inquiry and omissions were harmless. The court held that defendant failed to prove by clear and convincing evidence that there was double patenting. Accordingly, the court affirmed.

OUTCOME: The judgment was affirmed because the expert opinion was admissible without the need to reveal underlying facts. The omission of references to prior art for determining obviousness were harmless because the references did not disclose or suggest the features critical to the invention's patentability and were immaterial.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Infringement > Burdens of Proof
[HN1] The party asserting infringement bears the burden of proof by a preponderance of the evidence.

Patent Law > Infringement > Acts of Infringement
[HN2] Determination of patent infringement is a two-step process: the meaning of the claims must be learned from a study of all relevant patent documents; and the claims must be applied to the accused structures.

Evidence > Witnesses > Expert Testimony
[HN3] See Fed. R. Evid. 705.

Patent Law > Specification & Claims > Claim Language
[HN4] By its express terms, *35 U.S.C.S. § 112,* para. 6 permits an element in a claim to be expressed as a means or step for performing a specified function. However, the scope of such a claim is not limitless, but is confined to structures expressly disclosed in the specification and corresponding equivalents. Thus, the statutory provision prevents an overly broad claim construction by requiring reference to the specification, and at the same time precludes an overly narrow construction that would restrict coverage solely to those means expressly disclosed in the specification.

Evidence > Witnesses > Expert TestimonyPatent Law > Infringement > Claim InterpretationPatent Law > Infringement > Burdens of Proof

[HN5] Testimony on the ultimate issue of infringement is permissible in patent cases. Although claim interpretation is a question of law, expert testimony is admissible to give an opinion on the ultimate question of infringement. Fed. R. Evid. 704. The scope of literally infringing "equivalents" under *35 U.S.C.S. § 112,* para. 6 is a factual determination. The full burden of exploration of the facts and assumptions underlying the testimony of an expert witness is squarely on the shoulders of opposing counsel's cross-examination.

Evidence > Witnesses > Expert TestimonyPatent Law > Infringement > Claim Interpretation

[HN6] Fed R. Evid. 705 is fully applicable to patent trials and opinion testimony on infringement of claims under *35 U.S.C.S. § 112* para. 6. The Federal Rules of Evidence are expressly applicable to all proceedings in the courts of the United States, which must include civil suits arising under Title 35. Fed. R. Evid. 101.

Patent Law > Nonobviousness > Tests & Proof of ObviousnessPatent Law > Infringement > Defenses

[HN7] In determining invalidity for obviousness, a court must answer whether the prior art made obvious the invention as a whole for which patentability is claimed. The court does not pick and choose among the individual elements of assorted prior art references to recreate the claimed invention, but rather looks for some teaching or suggestion in the references to support their use in the particular claimed combination.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN8] *35 U.S.C.S. § 103* requires consideration, inter alia, of differences between prior art and claimed invention as a whole.

Patent Law > Novelty & AnticipationPatent Law > Nonobviousness > Tests & Proof of Obviousness

[HN9] While a reference must enable someone to practice the invention in order to anticipate under *35 U.S.C.S. § 102*(b), a non-enabling reference may qualify as prior art for the purpose of determining obviousness under *35 U.S.C.S. § 103.*

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN10] The obviousness inquiry correctly includes review of the evidence offered on the objective indicia of nonobviousness, which included the failure of others to develop the claimed invention and its commercial success. Nonobviousness is suggested by the failure of others to find a solution to the problem which the patents in question purport to solve. Such evidence shows indirectly the presence of a significant defect in the prior art, while serving as a simulated laboratory test of the obviousness of the solution to a skilled artisan.

Patent Law > Nonobviousness > Double Patenting & Terminal Disclaimers

[HN11] With regard to double patenting, *35 U.S.C.S. § 121* will not apply to remove the parent as a reference where the principle of consonance is violated. Consonance requires that the line of demarcation between the independent and distinct inventions that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement. Where that line is crossed the prohibition of the third sentence of § 121 does not apply.

Patent Law > Nonobviousness > Double Patenting & Terminal Disclaimers

[HN12] See *35 U.S.C.S. § 121.*

Patent Law > Nonobviousness > Tests & Proof of ObviousnessPatent Law > Nonobviousness > Double Patenting & Terminal Disclaimers

[HN13] New or amended claims in a divisional application are entitled to the benefit of *35 U.S.C.S. § 121* if the claims do not cross the line of demarcation drawn around the invention elected in the restriction requirement. If that line is crossed, the issue is whether the invention claimed in the later patent would have been obvious in light of the invention claimed in the earlier patent.

Patent Law > Patentable Subject Matter > ProductsPatent Law > Patentable Subject Matter > Processes

[HN14] In the electronic arts, the Patent and Trademark Office has not restricted between claims to an apparatus and to a method of using the apparatus.

Patent Law > Nonobviousness > Double Patenting & Terminal Disclaimers

[HN15] The crux of obviousness-type double patenting inquiry lies in comparison of claims. The judicially created doctrine of obviousness-type double patenting applies when two applications or patents, not drawn to precisely the same invention, are drawn to inventions so very much alike as to render one obvious in view of the other and to effectively extend the life of the patent that would have the earlier of the two issue dates.

Patent Law > Nonobviousness > Double Patenting & Terminal DisclaimersPatent Law > Infringement > Burdens of Proof

[HN16] Double patenting is an affirmative defense, requiring defendant to prove double patenting by clear and convincing evidence.

Patent Law > Jurisdiction & Review > Standards of Review

[HN17] To obtain reversal, appellant must clearly explain why decision below is wrong. It is not the function of an appellate court to search the record in order to reach a conclusion favoring appellant.

Patent Law > Infringement > Claim InterpretationPatent Law > Jurisdiction & Review > Standards of Review

[HN18] The presence or absence of consonance will necessarily depend upon analysis of the involved claims, which are construed as a matter of law. In connection with construing claims, an appellate court is free to examine the prosecution history on appeal even where the trial court erroneously fails to consider it. This is particularly so where there are no underlying findings of fact required for such construction.

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect

[HN19] A finding of gross negligence does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.

COUNSEL:

Arnold Sprung, Sprung Horn Kramer & Woods, of Tarrytown, New York, argued for Plaintiff-Appellee. With him on the brief were Nathaniel D. Kramer and Ira J. Schaefer.

Jeffrey A. Schwab, Abelman Frayne Rezac & Schwab, of New York, New York, argued for Defendants-Appellants. With him on the brief was Michael Aschen.

JUDGES:

Nies, Chief Judge, Newman, and Clevenger, Circuit Judges.

OPINIONBY:

CLEVENGER

OPINION:

[*1571] CLEVENGER, Circuit Judge

Symbol Technologies, Inc., (Symbol) sued Opticon, Inc., and its Japanese parent Opto Electronics, (collectively hereinafter Opticon), in the United States District Court for the Southern District of New York for infringement of certain claims of United [*1572] States Patent Nos. *4,387,297* (*'297* patent), *4,593,186* (*'186* patent), and *4,409,470* (*'470* patent).

Symbol alleged that Opticon's MSH-840, MSH-850 and MSH-860 devices were infringing. Opticon denied infringement and filed a counterclaim for a declaratory judgment that the *'297* and *'186* patents are invalid and unenforceable. Following a non-jury trial, the District Court concluded that the *'297* and *'186* patents were not proved invalid or unenforceable, [**2] and found infringement. n1 *Symbol Technologies, Inc. v. Opticon, Inc., 17 U.S.P.Q.2d 1737, 1990 U.S. Dist. LEXIS 5186 (S.D.N.Y. 1990).* The court entered a liability judgment for Symbol.

n1 The District Court found that (1) the MSH-840 device infringes (i) claims 1-3, 8, 11, 15, 20, 23 and 36-38 of the *'297* patent, (ii) claims 1-8 and 11-15 of the *'186* patent when used with the decoder with which it was designed to operate and (iii) claims 1-5, 27, 31, 33, 50-54 and 56-62 of the *'470* patent; (2) the MSH-850 device infringes (i) claims 1-3, 8, 9, 11, 15, 17, 20, 23, and 36-38 of the *'297* patent, (ii) claims 1-9 and 11-15 of the *'186* patent when used with the decoder with which it was designed to operate; (3) the MSH-860 device infringes (i) claims 1-3, 5, 6, 8, 11, 15, 20, 21, 23, 36, and 37 of the *'297* patent and (ii) claims 1-9 and 11-15 of the *'186* patent when used with the decoder with which it was designed to operate.

Opticon appeals the judgment of the District Court. This Court has jurisdiction under *28 U.S.C. § 1292*(c)(2) [**3] (1988) to entertain Opticon's appeal. Because no reversible error was committed, we affirm.

I. BACKGROUND

The patents relate to devices that employ lasers to read bar code symbols, and methods of their use. The application that issued as the *'297* patent was filed on February 29, 1980. In the first official action, the examiner required restriction to one of seven species identified as Groups I - VII. The applicants elected Group I claims directed to a light-weight laser scanning head, which matured into the *'297* patent.

The *'297* patent specification refers to two types of previously known laser scanning devices. The first type, often mounted in supermarket and other checkout counters, requires a user to bring the symbol-bearing object to the stationary scanner. Its usefulness is limited to decoding symbols on objects that can be brought to the device. The second type uses a wand or pen that emits a scanning laser beam. The user places the pen in physical contact with the object, then manually drags the pen across the symbol. This second type requires user training because successful decoding depends on pen angle, pressure, and speed of passage as the pen is dragged across the bar [**4] code. Multiple passes of the pen are often required to achieve a single reading. Moreover, the tips of pen scanners tend to scar the bar codes and are not useful on wax coated containers, such as milk cartons, on soft products, such as bagged potato chips, or on reflective aluminum cans.

In contrast, the invention claimed in the *'297* patent is a portable, light-weight laser scanning head that operates without physical contact with the bar code. *See* Figure 1. In gun-like fashion, the user sights the bar code, unobstructed by the device, then depresses a trigger to initiate decoding. Each time the trigger is depressed, the hand-held device sweeps a scanning laser beam laterally across the bar code by use of mirrors. The examiner considered this "aim and shoot" feature to be a novel distinguishing characteristic of the claimed invention over the prior art. All of the asserted *'297* patent claims depend on claim 1, reprinted in the Appendix, which in pertinent part claims the "aim and shoot" feature as:

> (c) miniature optic means . . . to permit the user to conveniently register the laser light beam on the symbol by sighting the symbol along a direct line of sight which does not pass [**5] through the housing;
> (d) miniature scanning means mounted in the light path and in the interior space of the housing for cyclically sweeping the laser light beam across the bar code symbol for reflection therefrom;
>
> * * *
>
> (h) handle means for normally supporting the light-weight laser scanning head in a non-contacting relationship with the symbol during reading thereof; and
> [*1573] (i) manually actuatable trigger means on the housing for initiating reading of the symbol each time the trigger means is manually actuated by the user.

[SEE FIGURE 1 IN ORIGINAL]

Before the *'297* patent issued, the applicants filed a divisional application directed to the originally non-elected Group VI claims, described in the restriction as a "method" of scanning, sensing and decoding bar code symbols. Thereafter, the applicants filed a continuation of the divisional application, which eventually issued as the *'186* patent. The *'186* patent contains apparatus claims 1-10 and method claims 11-15, with the method claims closely corresponding to the original Group VI claims. The broadest asserted apparatus and method claims, reprinted in the Appendix, both require a "trigger" and "repetitively" scan [**6] "the directed laser beam across each symbol for reflection therefrom." Thus, the *'186* patent claims a system that repetitively scans and senses a bar code symbol each time a user depresses the trigger. Each symbol is decoded from repetitive rather than single scans, thereby increasing the likelihood of achieving accurate decoding even for poorly printed symbols. In addition, claim 1 and claim 11 include limiting language for "determining a successful decoding of each symbol," and for "non-manually terminating the reading of each symbol upon the determination of the successful decoding thereof." *See* Appendix. Thus, the invented system alerts the user and automatically stops scanning when the symbol is decoded, permitting rapid and sequential decoding of multiple objects.

The same applicants claimed an advance over the invention of the *'297* patent in an application filed on January 25, 1982, which later issued as the *'470* patent. The *'470* patent specification explains that, because the scanning laser beam of the invention [*1574] claimed in the *'297* patent passes through the inside of the device, "a great deal of interior 'dead' space within the head" is required in order to accommodate [**7] the scanning beam.

In contrast, the *'470* patent discloses a scanning head with a raised rear window that emits the laser beam over the outside top of the device rather than inside its housing. Claim 1 of the *'470* patent, reprinted in the Appendix, includes:

> (g) window means mounted on the housing, and having a light-transmissive window at the rear region in close adjacent confronting relationship with the scanning means thereat, said window being configured and positioned in the light path of said at least one swept beam to permit the latter to pass through the window and unobstructedly travel exteriorly of and past the front and intermediate body regions of the housing.

> whereby the field of view of the swept beam is substantially independent of the predetermined width of the housing due to its exterior transmission outside of the front and intermediate body regions of the housing.

Thus, since the device no longer must accommodate the sweep width of the scanning beam, the invention allows a narrowing of the body of the device, with a corresponding reduction in overall size and weight.

II. INFRINGEMENT

Opticon's first contention on appeal is that Symbol presented insufficient [**8] evidence during its case-in-chief to establish a prima facie showing of infringement. Symbol, as [HN1] the party asserting infringement, bore the burden of proof by a preponderance of the evidence. *Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1361, 219 U.S.P.Q. (BNA) 473, 480 (Fed. Cir. 1983).*

To prove infringement, Symbol offered the expert testimony of Mr. Edward Barkan (Barkan), named as a co-inventor in each of the three patent applications. The court admitted into evidence charts and drawings used by Barkan to demonstrate infringement of the asserted claims, each of which contains "means plus function" limitations as permitted under *35 U.S.C. § 112* para. 6 (1988). The charts show each asserted claim broken down by limitation, with one or more numbers placed next to each limitation. Corresponding numbers identify various structural parts of the accused devices depicted in the drawings. Using the exhibits as a guide, Barkan stated that in his opinion each numbered claim limitation reproduced on the charts was met by the corresponding numbered structure of the device shown on the drawings. Furthermore, Barkan testified that his "understanding of the patent [**9] claims [was] based upon the claims, as well as the specifications, as well as statements made during the prosecution history."

[HN2] Determination of patent infringement is a two-step process: "the meaning of the claims must be learned from a study of all relevant patent documents; and the claims must be applied to the accused structures." *Caterpillar Tractor Co. v. Berco, S.P.A., 714 F.2d 1110, 1114, 219 U.S.P.Q. (BNA) 185, 187 (Fed. Cir. 1983).* Opticon contends that, under *Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 934, 4 U.S.P.Q.2d (BNA) 1737, 1739 (Fed. Cir. 1987), cert. denied, 485 U.S. 961, 99 L. Ed. 2d 426, 108 S. Ct. 1226 (1988),* a party asserting infringement of claims with "means plus function" limitations must demonstrate to the fact-finder how each structure in the accused device, asserted to meet a functional claim limitation, is the same as or equivalent to a corresponding structure disclosed in the specification. Opticon cites the following passage from *Pennwalt* for support:

> Where the issue is raised, it is part of the ultimate burden of proof of the patent owner to establish, with respect to a claim limitation in means-plus-function [**10] form, that the structure in the accused device which performs that function is the same as or an equivalent of the structure disclosed in the specification.

Id.

In the circumstances of this case, however, Fed. R. Evid. 705 provides the answer to whether Symbol made a prima facie [*1575] showing of infringement. n2 At trial, Symbol suggested that the court receive the exhibits representing Barkan's expert testimony without foundation, thus relieving the court and Barkan of the need to "go through lengthy testimony explaining with each infringing device how he found that each element was infringed." Counsel for Opticon responded "I really have no objection except . . . that we have wanted to voir dire." After voir dire, Opticon failed to cross-examine Barkan on the issue that it now asserts fatally flaws the sufficiency of his testimony.

n2 Rule 705, "Disclosure of Facts or Data Underlying Expert Opinion," provides: [HN3]

> The expert may testify in terms of opinion or inference and give reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.

----------End Footnotes----------

[HN4] - [**11]

By its express terms, § 112 para. 6 permits an element in a claim to be expressed as a means or step for performing a specified function. However, the scope of such a claim is not limitless, but is confined to structures expressly disclosed in the specification and corresponding equivalents. Thus, the statutory provision prevents an overly broad claim construction by requiring reference to the specification, and at the same time

precludes an overly narrow construction that would restrict coverage solely to those means *expressly* disclosed in the specification. *Johnston v. IVAC Corp., 885 F.2d 1574, 1580, 12 U.S.P.Q.2d (BNA) 1382, 1386-87 (Fed. Cir. 1989)* (statutory provision acts as restriction on claim scope); *Data Line Corp. v. Micro Technologies, Inc., 813 F.2d 1196, 1201, 1 U.S.P.Q.2d (BNA) 2052, 2055 (Fed. Cir. 1987)* (statutory provision precludes a construction limited to structures expressly disclosed in specification); *D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574, 225 U.S.P.Q. (BNA) 236, 238 (Fed. Cir. 1985)* (statutory provision requires that "limitation *shall* be construed to cover structure described [**12] in the specification *and* equivalents thereof" (emphasis in original)). In short, applying a claim drafted under § 112 para. 6 to an accused structure is not a simple task.

Opticon argues that Barkan must have misunderstood this task, because he testified on the ultimate issue of infringement without discussing in detail equivalency between the structures of the accused devices and the structures disclosed in the patent specifications. However, [HN5] testimony on the ultimate issue of infringement is permissible in patent cases. *Snellman v. Ricoh Co., 862 F.2d 283, 287, 8 U.S.P.Q.2d (BNA) 1996, 2000 (Fed. Cir. 1988), cert. denied, 491 U.S. 910, 109 S. Ct. 3199, 105 L. Ed. 2d 707 (1989)* ("although claim interpretation is a question of law, expert testimony is admissible . . . to give an opinion on the ultimate question of infringement" (citations omitted)); Fed. R. Evid. 704. The scope of literally infringing "equivalents" under § 112 para. 6 is a factual determination. *King Instrument Corp. v. Otari Corp., 767 F.2d 853, 862, 226 U.S.P.Q. (BNA) 402, 408 (Fed. Cir. 1985), cert. denied, 475 U.S. 1016, 89 L. Ed. 2d 312, 106 S. Ct. 1197 (1986).* The responsibility for challenging [**13] the factual underpinnings of the testimony fell squarely on Opticon during cross-examination. *See Smith v. Ford Motor Co., 626 F.2d 784, 793 (10th Cir. 1980), cert. denied, 450 U.S. 918, 67 L. Ed. 2d 344, 101 S. Ct. 1363 (1981)* ("'the full burden of exploration of the facts and assumptions underlying the testimony of an expert witness [is] squarely on the shoulders of opposing counsel's cross-examination'" (citation omitted)); *see also Bryan v. FMC Corp., John Bean Div., 566 F.2d 541, 545 (5th Cir. 1978)* ("rule 705 shifts to the cross-examiner the burden of eliciting the bases of an expert witness' opinion"); *United States v. Santarpio, 560 F.2d 448, 454-55 (1st Cir. 1977), cert. denied sub nom., Schepici v. United States, 434 U.S. 984, 54 L. Ed. 2d 478, 98 S. Ct. 609 (1977)* (under Rule 705, court was entitled to credit expert's conclusion even though expert did not describe and explain the relevance of factors upon which his opinion rested; defendant neither cross-examined on basis for opinion nor attempted to show its inadequacy); *C. Van Der Lely, N.V. v. F. Ili Maschio S.n.c., 221 U.S.P.Q. (BNA) 34, 41 (S.D. Ohio 1983), aff'd, 748 F.2d 1568* [*1576] *(Fed. Cir. 1984)* [**14] (under Rule 705, "cross-examination [is] the proper procedure for the defendant to challenge the accuracy of [the expert's] opinion"). Opticon failed to seize the opportunity, provided by the Rule, to demonstrate that Barkan's opinion testimony was factually incorrect.

Rule 705 functions to abbreviate trials by permitting opinion testimony without factual foundation. We see no reason why [HN6] Rule 705 is not fully applicable to patent trials and opinion testimony on infringement of claims under § 112 para. 6. We have not directly addressed this issue, but have previously applied Rule 705 in a patent case on the issue of damages, stating that an expert need not "reveal the facts or data underlying his opinion . . . because [the defendant] did not cross-examine on this issue and the master did not require otherwise." *Studiengesellschaft Kohle v. Dart Indus., 862 F.2d 1564, 1567, 9 U.S.P.Q.2d (BNA) 1273, 1277 (Fed. Cir. 1988).* Moreover, the Federal Rules of Evidence are expressly applicable to all proceedings in the courts of the United States, which must include civil suits arising under Title 35. Fed. R. Evid. 101. Finally, the specific purpose behind Rule 705 is to [**15] avoid "complex and time consuming" testimony by permitting an expert to "'state his opinion and reasons without first specifying the data upon which it is based.'" Fed. R. Evid. 705 advisory committee's note *quoting* Rule 4515, N.Y. CPLR (McKinney 1963). Patent cases, so often typified by lengthy testimony on complex technical issues, are particularly served by this purpose.

In short, Symbol was permitted to rest its prima facie case on Barkan's expert testimony, including charts, that the patents were infringed, and the District Court was free to accept or reject that evidence. Of course, by resting its case on summary testimony, Symbol was left exposed to a profound risk that Opticon, during its defense or cross-examination of Barkan, would demonstrate that the accused devices were non-infringing under a different and proper construction of the claims. Opticon willingly permitted Symbol to bear this risk, but chose not to expose Barkan's testimony to the glaring light of cross-examination on this issue. Having lost below, Opticon cannot here recoup for its failed litigation strategy. n3 In view of the legal effect of the expedited procedure, we must reject Opticon's contention [**16] that Symbol failed to present a prima facie case of infringement. Since Opticon offers no argument that its products do not infringe on the facts, we need not review infringement itself.

n3 *See* 3 J. Weinstein & M. Berger, Weinstein's Evidence para. 705[01], p. 705-11 (1987):

> Obviously, if further testimony would only solidify the expert's conclusion, his adversary will refrain from further questioning. But if he concludes that the expert has omitted pertinent facts in arriving at his opinion, or has misconstrued them, or is accepting disputed facts as true, or is basing his opinion on someone else's opinion which is in conflict with the established facts, the attorney will wish to probe into the expert's premises.

III. VALIDITY

A. *Obviousness*

Opticon challenges the District Court's conclusion that the inventions of the *'297* and *'186* patents were not proved invalid for obviousness under *35 U.S.C. § 103* (1988). n4 [HN7] We must answer whether "the prior art made obvious the invention as a whole for which patentability [**17] is claimed." *Hartness Int'l Inc. v. Simplimatic Eng'g Co., 819 F.2d 1100, 1108, 2 U.S.P.Q.2d (BNA) 1826, 1832 (Fed. Cir. 1987).* We do not "pick and choose among the individual elements of assorted prior art references to recreate the claimed invention," but rather, we look for "some teaching or suggestion in the references to support their use in the particular claimed combination." *Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 887, 8 U.S.P.Q.2d (BNA) 1468, 1475 (Fed. Cir. 1988).*

n4 The District Court focused on the obviousness of the invention claimed in the *'297* patent. Opticon offers no separate argument on the obviousness under § 103 of the invention claimed in the *'186* patent. We therefore limit our review to the obviousness *vel non* of the invention of the *'297* patent.

[*1577] The District Court found that the prior art consisted of U.S. Patent No. *4,251,798* (the *'798* patent), which describes the Laserchek, and references which describe the Laserscan, [**18] the Verifier 315, the Monitor 101, and the Carton Counter. We review here the teachings of that art.

The *'798* patent is prior art under *35 U.S.C. § 102*(e) (1988). The *'798* patent claims a portable laser scanning head that detects and decodes laser beams reflected from bar codes. The reference discloses a device that can read in a non-contact position:

> This 'depth of field' feature permits a user to scan bar code symbols imprinted both on a flat surface and on a curved surface merely by moving the head towards a position anywhere within 2" of the symbol.

'798 patent, col. 5, line 66 - col. 6, line 6.

During prosecution of the *'297* patent, the *'798* patent was the basis for discussions about the permissible scope of the *'297* patent claims. Indeed, the examiner originally rejected the claimed invention as obvious in light of the disclosure in the *'798* patent. Following an interview with the examiner, the applicants amended the claims to include the handle, trigger and sighting means that appear in claim 1 and are quoted above. The examiner allowed the claims in view of the amendment. The District Court agreed with the examiner's conclusion that the addition of the handle, trigger [**19] and sighting means (described by the District Court as the "aim and shoot" feature) to the self-scanning means distinguished the invention claimed in the *'297* patent from the disclosure in the *'798* patent.

The Laserchek device, a Symbol product, is described in the *'798* patent. Following a demonstration of the device at trial, the District Court found that the Laserchek was a bar code verification device, had no trigger, normally blocked the user's view of the bar code during use, and could not be used in the "aim and shoot" fashion.

The Laserscan was merely a modified version of the Laserchek. The Laserscan consisted of the Laserchek scanning head attached to a console in turn attached to a computer. The District Court found that the Laserscan was not capable of functioning in "aim and shoot" mode because the device had no trigger and obscured the bar code during use.

The Verifier 315 was a bar code reader designed to be used with its feet resting on a surface and its front reading "snout" positioned above the bar code by a small, fixed distance. The District Court found that the device blocked the user's view of the bar code during use and had no trigger.

The Monitor 101 was developed [**20] in the mid-1970's to verify the accuracy of bar codes as they are printed. During printing, the bar codes pass underneath the device, which is fixed above the printing press. The District Court found that the Monitor 101 was neither hand held nor capable of operating in "aim and shoot" fashion.

The Carton Counter counted cartons and was not a bar code reader. However, the device had a trigger, not to initiate decoding of a bar code, but to reset the counter to zero. A brochure describing the Carton Counter was before the examiner and found not to be pertinent. The District Court, finding that the carton counter "is not self-scanning; rather, it must be dragged over the carton edges," concluded that the device "lacks any disclosure, recognition, or teaching of an aim and shoot device." *17 U.S.P.Q.2d at 1746.*

The District Court thus concluded that the invention would not have been obvious in light of the prior art because the considered references did not disclose or suggest the "aim and shoot" feature claimed in parts (c), (d), (h) and (i) of claim 1 of the *'297* patent. We agree. Here the very difference between the claims and the considered art is the "aim and shoot" feature [**21] found critical to the patentability of the invention. *Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 U.S.P.Q. (BNA) 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966)* [HN8] (§ 103 requires consideration, *inter alia*, of differences between prior art and claimed invention as a whole). Thus, a person of ordinary skill in the art, having all of the [*1578] teachings of the considered references before him, would have found no "teaching or suggestion in the references" of the invention claimed in the *'297* patent. *Smithkline Diagnostics, 859 F.2d at 887, 8 U.S.P.Q.2d at 1475.*

However, in reaching its conclusion, the District Court excluded sketches and tentative specifications relating to a device known as the X-Scanner, on the theory that "'prior art' in an obviousness determination [] must . . . be enabling, that is, disclose the disseminated subject matter to the public, in a manner such that one skilled in the art could make and operate such a device." *17 U.S.P.Q.2d at 1740.* [HN9] While a reference must enable someone to practice the invention in order to anticipate under § 102(b), a non-enabling reference may qualify as prior art for the purpose of determining obviousness [**22] under § 103. *Reading & Bates Constr. Co. v. Baker Energy Resources Corp., 748 F.2d 645, 652, 223 U.S.P.Q. (BNA) 1168, 1173 (Fed. Cir. 1984)* (reference that lacks enabling disclosure is not anticipating, but "itself may qualify as a prior art *reference* under § 103, but only for what is disclosed in it" (emphasis in original)); *see Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551, 13 U.S.P.Q.2d (BNA) 1301, 1304 (Fed. Cir. 1989)* ("even if a reference discloses an inoperative device, it is prior art for all that it teaches"). Undisputed evidence demonstrated that the sketches and tentative specifications, together known as the X-Scanner reference, were publicly available more than one year before the effective filing date. The District Court's finding to the contrary is clearly erroneous. While the District Court clearly erred in excluding the X-Scanner sketches and tentative specifications from the prior art for the purpose of evaluating obviousness under § 103, that error did not preclude the District Court from alternatively reaching its factual conclusions regarding those materials. The District Court specifically stated, [**23] in pertinent part, that "the 'X-Scanner' had to be dragged across the symbol rather than being aimed and shot." *17 U.S.P.Q.2d at 1747.*

The X-Scanner reference discloses a 2 lb. laser scanning head for reading bar code symbols at a maximum working range of 4" from the bar code. Thus, like the *'798* patent, the reference discloses a device capable of reading in a non-contact position. The disclosed device has a trigger, and may be used in either "portable mode" or "permanent mount mode." When operated in permanent mount mode, the device scans continuously from a fixed position above the bar code, much like the Verifier 315 already considered. The reference explains that the device, when operated in portable mode, has a "0-2 seconds scan duration" which is activated by a "trigger." In both modes, the laser beam puts out an "X" pattern and the "symbol must move across [the scanning] field, or vice versa."

In support of its conclusion that the X-Scanner had to be dragged across the symbol rather than aimed and shot, the District Court cited the expert testimony of Symbol's expert witness, Mr. Swartz. Swartz testified that the X-Scanner's "mode of use" was sufficiently different [**24] from the invention of the *'297* patent that it was "not a device that is used in a shoot mode, [] because it is, it creates an X-pattern as shown." Therefore, to obtain a reading, "you cannot do it stationary, you must have relative motion [between the symbol and device]." Swartz also stated "you would have to move [the scan head], you could not use it in aim and shoot mode." Opticon's evidence to the contrary failed to persuade the District Court, and Opticon has failed to persuade us that the District Court committed reversible error in crediting Symbol's evidence on this point.

[HN10] The obviousness inquiry conducted by the District Court correctly included review of the evidence offered on the objective indicia of nonobviousness, *Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538, 218 U.S.P.Q. (BNA) 871, 879 (Fed. Cir. 1983),* which included the failure of others to develop the claimed

invention and its commercial success. Nonobviousness is suggested by the failure of others to "find a solution to the problem which the patent[s] in question purport[] to solve. Such evidence [*1579] shows indirectly the presence of a significant defect [in the prior art], while serving [**25] as a simulated laboratory test of the obviousness of the solution to a skilled artisan." Note, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity, 112 U. Pa. L. Rev. 1169, 1173 (1964).* On this issue, the District Court found that Opticon's own expert witness, Mr. Collins, was "closely involved with the bar code industry since its inception and [] never conceived or developed an aim and shoot scanning device." *17 U.S.P.Q.2d at 1747.* The court further found that, despite years of effort, Opticon's technical witness, Mr. Knowles, was "never able to develop a scanner with the aim and shoot feature of the patents in suit." *Id.* Furthermore, as found by the District Court, Symbol's "aim and shoot" scanners have enjoyed tremendous commercial success, with about 200,000 devices sold for over $ 150,000,000 as of the time of trial. These findings are not challenged by Opticon.

In short, under the evidence that was put forward by Symbol and properly accepted by the court, the omitted reference adds nothing to the scope of the already considered prior art except a trigger in a bar code reader. This addition is minor, because the Carton Counter already [**26] discloses a trigger, although in a device for counting cartons. When the X-Scanner reference is considered with all the other references, the prior art as a whole still lacks a disclosure or suggestion of the "aim and shoot" feature, in which a laser beam sweeps laterally across the bar code while the hand-held device is held stationary and the target can be viewed.

We thus conclude that, even when the X-Scanner reference is included in the prior art, Opticon has not met its burden of proving that the inventions of the *'297* and *'186* patents would have been obvious under § 103. The District Court's error in alternatively excluding the X-Scanner reference from the prior art was therefore harmless.

B. *Double Patenting*

Opticon challenges the District Court's conclusion that the *'186* patent was not invalid for obviousness-type double patenting over the *'297* patent. After the examiner required restriction during prosecution of the *'297* patent, the applicants filed a divisional application containing method claims drawn to the invention of the originally non-elected Group VI claims. A continuation of the divisional containing both the old method and new apparatus claims eventually [**27] issued as the *'186* patent.

[HN11] With regard to double patenting, we recently explained that *35 U.S.C. § 121* (1988) n5 will not apply to remove the parent as a reference where the principle of consonance is violated:

> Consonance requires that the line of demarcation between the "independent and distinct inventions" that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement. Where that line is crossed the prohibition of the third sentence of Section 121 does not apply.

Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 688, 16 U.S.P.Q.2d (BNA) 1436, 1440 (Fed. Cir. 1990).

n5 Section 121 provides, in relevant part:

> [HN12] A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

[**28]

The corollary to this Court's statement in *Gerber Garment* is that [HN13] new or amended claims in a divisional application are entitled to the benefit of § 121 if the claims do not cross the line of demarcation drawn around the invention elected in the restriction requirement. If that line is crossed, the issue is whether the invention claimed in the *'186* patent would have been obvious in light of the invention claimed in the *'297* patent.

[*1580] Opticon contends, as it did before the trial court, that the appearance of "a whole *new* group of apparatus claims along with the method claims" in the

'186 patent proves that the claims "asserted against Opticon are drawn to the elected species of the *'297* patent and not the species upon which the divisional was filed." We read Opticon's bare assertions in its opening brief, without record citation, to allege that because the Group VI invention was described as a "method" in the restriction requirement, the added *apparatus* claims fail to comply with the requirement. The District Court had before it the declaration of Mr. Berger, which fully supports a conclusion that both the method and apparatus claims are directed to the Group VI invention. [**29] Berger stated that the Group VI invention is a system of scanner plus decoder, with a means for stopping the scanner after the symbol is successfully decoded. Therefore, whether method or apparatus, all the *'186* patent claims are drawn to that system. Berger further asserted that [HN14] in the electronic arts, the Patent and Trademark Office (PTO) has not restricted between claims to an apparatus and to a method of using the apparatus. *Cf. Studiengesellschaft Kohle v. Northern Petrochemical Co., 784 F.2d 351, 354, 228 U.S.P.Q. (BNA) 837, 840 (Fed. Cir. 1986), cert. dismissed, 478 U.S. 1028, 92 L. Ed. 2d 763, 106 S. Ct. 3343 (1986)* (chemical composition claims defined invention different from process claims). In short, Berger explained that the word "method" in the description of Group VI during restriction did not mean that the *claims* were limited to a method, but was merely a short-hand description of the invented *system*. For support, Berger stated that the examiner collectively characterized the method and apparatus claims of another non-elected group, Group IV, as a "method." Finally, Berger noted that the examiner's statement that "the Group I invention does not require [**30] the particular *apparatus* of Group . . . VI," (emphasis added) cannot be reconciled with Opticon's argument that the invention of Group VI could only be expressed as a method. In light of this testimony, we cannot agree that a breach of the restriction requirement occurred. The safeguard of § 121 therefore applies in this case, and the *'297* patent is not available as a reference against the *'186* patent.

Furthermore, even if there had been a breach of the restriction requirement, we would reject Opticon's argument on the ultimate obviousness-type double patenting inquiry: whether the claims of the *'186* patent are patentably distinct from the claims of the *'297* patent. *See In re Borah, 53 C.C.P.A. 800, 354 F.2d 1009, 1017, 148 U.S.P.Q. (BNA) 213, 220 (CCPA 1966)* [HN15] (crux of obviousness-type double patenting inquiry lies in comparison of claims); *see also Gerber Garment, 916 F.2d at 686, 16 U.S.P.Q.2d at 1438* (judicially created doctrine of obviousness-type double patenting applies when two applications or patents, not drawn to precisely the same invention, are "drawn to inventions so very much alike as to render one obvious in view of the other and to [**31] effectively extend the life of the patent that would have the earlier of the two issue dates").

[HN16] Double patenting is an affirmative defense. *Studiengesellschaft Kohle v. Northern Petrochemical Co., 784 F.2d at 352, 228 U.S.P.Q. at 838.* Opticon was therefore required to prove double patenting by clear and convincing evidence, a heavy and unshifting burden. *RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 U.S.P.Q. (BNA) 385, 387 (Fed. Cir. 1984)* (invalidity requires clear and convincing proof, and burden remains at all times with patent challenger); *Carman Indus., Inc. v. Wahl, 724 F.2d 932, 940, 220 U.S.P.Q. (BNA) 481, 487 (Fed. Cir. 1983)* ("there is a heavy burden of proof on one seeking to show double patenting").

Opticon's conclusory allegation that the District Court's decision on double patenting was in error, without citation to the record, the patents or the testimony of the witnesses, does not support reversal. *See In re Mulder, 716 F.2d 1542, 1550, 219 U.S.P.Q. (BNA) 189, 197 (Fed. Cir. 1983)* (to [HN17] obtain reversal, appellant must clearly explain why decision below [**32] is wrong). As a court of review, it is not our function to search the voluminous trial record, prosecution histories, and patents to fashion a substantive [*1581] basis for Opticon's argument. *See Preemption Devices, Inc. v. Minnesota Mining & Mfg. Co., 732 F.2d 903, 905, 221 U.S.P.Q. (BNA) 841, 842 (Fed. Cir. 1984)* (as appellate court, it is not our function to search the record in order to reach a conclusion favoring appellant).

Nevertheless, even a brief review of the *'297* patent reveals that all of the asserted claims are directed to a laser self-scanning head with a "trigger," a "handle," and means for "sighting the symbol along a direct line of sight." In contrast, the asserted claims of the *'186* patent recite additional features. Although the claims of the *'186* patent cover a laser scanning system that includes a portable laser scanning head, the system also includes means for *repetitively* self scanning a bar code symbol until it is decoded. Furthermore, when successful decoding has been achieved, the system alerts the user and automatically stops scanning. The repetitive scan feature adds the advantage of increasing the accuracy of decoding. Claim 8 includes [**33] a further feature of terminating the repetitive scan if no successful decode is achieved within a set time period.

Opticon contends in its reply brief that the automatic termination feature is merely an obvious addition to the invention claimed in the *'297* patent, because its expert testified that this feature "is a software program, essentially a software program, or firmware program, if you go back far enough in time." The mere reference to "a software program" does not demonstrate that the

program would have been obvious or that its addition to the invention of the *'297* patent would have been obvious.

Furthermore, the policy behind the double patenting doctrine, the prevention of unlawful extension of the patent grant, does not favor Opticon's position. Although the *'297* patent will expire before the *'186* patent, the *'186* patent will not "extend" the property right conveyed in the *'297* patent. *See Gerber Garment, 916 F.2d at 686, 16 U.S.P.Q.2d at 1438* (obviousness-type double patenting occurs when a second patent would "effectively extend the life of the patent that would have the earlier of the two issue dates"). Since the *'186* patent is not infringed [**34] by practice of the invention claimed in the *'297* patent, the world will be free to use the invention of the *'297* patent once it expires. *See In re Kaplan, 789 F.2d 1574, 1578, 229 U.S.P.Q. (BNA) 678, 681-82 (Fed. Cir. 1986)* (no double patenting found where no extension of patent right is possible because when the first to issue patent expires, "the world will be free to use" the first patented invention so long as the second patented invention is not used in it).

Finally, Opticon contends that the judgment of the District Court should be reversed for failure to state findings of fact under Fed. R. Civ. P. 52(a). On appeal, Opticon raises the issue of consonance. As this Court explained in *Gerber Garment*, [HN18] "the presence or absence of consonance will necessarily depend upon analysis of the involved claims," *916 F.2d at 688, 16 U.S.P.Q.2d at 1441*, which are construed as a matter of law. *Cf. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 n.3, 227 U.S.P.Q. (BNA) 543, 547 n.3 (Fed. Cir. 1985)* ("Under this court's precedent substantial identity between claims, a matter of claim interpretation, is a question [**35] of law."). In connection with construing claims, we are free to examine the prosecution history on appeal even where the trial court erroneously fails to consider it. *See Lemelson v. United States, 752 F.2d 1538, 1550, 224 U.S.P.Q. (BNA) 526, 532-33 (Fed. Cir. 1985)*. This is particularly so where, as here, there are no underlying findings of fact required for such construction. Because we have concluded that the claims of the *'186* patent are within the subject matter of Group VI as a matter of law, the absence of Rule 52(a) findings of fact on this issue is not reversible error.

We thus conclude that Opticon has failed to demonstrate that the District Court erred in finding that no claim in the *'186* patent was proved invalid for double patenting.

IV. ENFORCEABILITY

Opticon challenges the District Court's conclusion that neither the *'297* patent [*1582] nor the *'186* patent are unenforceable because of inequitable conduct during prosecution. Opticon reiterates its argument, considered and rejected below, that Symbol fraudulently withheld information from the examiner concerning the Verifier 315 and the Laserscan during prosecution of the *'297* and *'186* patents.

Opticon asserts [**36] that the District Court erroneously failed to consider references that Symbol "should have known" were material, citing *FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415, 5 U.S.P.Q.2d (BNA) 1112, 1116 (Fed. Cir. 1987)*. However, we have repeatedly rejected the simple negligence standard that Opticon urges us to adopt. *See, e.g., Jaskiewicz v. Mossinghoff, 822 F.2d 1053, 1058, 3 U.S.P.Q.2d (BNA) 1294, 1299 (Fed. Cir. 1987)* ("mere negligence is not sufficient to infer fraud or dishonesty"). Moreover, even [HN19] a finding of gross negligence:

> does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.

Kingsdown Medical Consultants v. Hollister Inc., 863 F.2d 867, 876, 9 U.S.P.Q.2d (BNA) 1384, 1392 (Fed. Cir. 1988), cert. denied, 490 U.S. 1067, 104 L. Ed. 2d 633, 109 S. Ct. 2068 (1989).

Opticon asserts that a flyer submitted by Symbol during reexamination depicted an operational Verifier 315, and that Symbol deceived the PTO by indicating that the flyer [**37] depicted only an empty shell or housing. The record is replete with evidence supporting a conclusion that, at the very least, Symbol possessed a good faith belief that the photograph in the flyer indeed depicted only an empty shell of an inoperable device, a belief to which the District Court, in the final analysis, itself concurred. Opticon further argues that Symbol improperly withheld from the examiner information relating to the Laserscan device during prosecution of its patents, but as noted *supra*, that device was a modified version of the Laserchek device disclosed in the *'798* patent. We conclude that the reference was merely cumulative to the teachings of the *'798* patent, imparting no obligation to disclose. *See J.P. Stevens & Co. v. Lex Tex, Ltd., 747 F.2d 1553, 223 U.S.P.Q. (BNA) 1089, 1092 (Fed. Cir. 1984), cert. denied, 474 U.S. 822, 88 L. Ed. 2d 60, 106 S. Ct. 73 (1985)* ("[a] reference that would have been merely cumulative is not material").

We find no abuse of discretion in the District Court's conclusion that the *'297* and *'186* patents were not proved unenforceable for inequitable conduct during prosecution.

V. CONCLUSION

Among other issues, Opticon alleges [**38] that the sparseness of the District Court's Rule 52 findings, particularly on infringement and double patenting, preclude effective appellate review. Our opinion amply demonstrates the absence of merit in that allegation. Having duly considered and rejected each of Opticon's other arguments, we affirm the judgment of the District Court.

AFFIRMED.

APPENDIX

The '297 Patent

1. In a laser scanning system for reading bar code symbols, a light-weight easy-to-manipulate laser scanning head normally supportable only by a user throughout the reading of the symbols, comprising:

(a) a housing having wall portions bounding an outlet port and bounding an interior space whose volume measures less than a value which is on the order of 100 cubic inches;

(b) a light source mounted in the interior space of the housing for generating a laser light beam;

(c) miniature optic means mounted in the interior space of the housing for directing the laser light beam along a light path through the outlet port and towards a bar code symbol which is located exteriorly of the housing by a distance sufficient to permit the user to conveniently register the laser light beam on the symbol by sighting the symbol [**39] along a direct line of sight which does not pass through the housing;

[*1583] (d) miniature scanning means mounted in the light path and in the interior space of the housing for cyclically sweeping the laser light beam across the bar code symbol for reflection therefrom;

(e) miniature sensor means mounted in the interior space of the housing for detecting the intensity of light reflected from the bar code symbol, and for generating an electrical signal indicative of the detected intensity of the reflected light;

(f) miniature signal processing means mounted in the interior space of the housing for processing the electrical signal to generate therefrom data descriptive of the bar code symbol;

(g) all of said light source, optic means, sensor means and signal processing means together with said housing comprising the light-weight laser scanning head whose total weight measures less than a value which is on the order of two pounds;

(h) handle means for normally supporting the light-weight laser scanning head in non-contacting relationship with the symbol during reading thereof; and

(i) manually actuatable trigger means on the housing for initiating reading of the symbol each time the trigger [**40] means is manually actuated by the user.

The '186 Patent

1. A laser scanning system for reading bar code symbols, each in its respective turn, comprising:

(a) a light-weight, hand-held head normally supportable by a user in a normally non-contacting relationship with the symbols during reading thereof, said head including therein

(i) means for generating a laser beam, and for directing the same along a light path through an outlet port of the head to each symbol,

(ii) scanning means for repetitively scanning the directed laser beam across each symbol for reflection therefrom,

(iii) sensor means for detecting the variable intensity of each scanned laser beam reflected from each symbol, and for generating an electrical signal indicative of the detected intensity for each symbol, and

(iv) signal processing means for processing each electrical signal, and for generating a processed electrical signal for each symbol;

(b) decoding means operatively associated with the signal processing means, for decoding the processed signal for each symbol to be read;

(c) manually actuatable trigger means on the head and operatively associated with the decoding means, for initiating reading of each [**41] symbol upon each manual actuation of the trigger means from one state to another state by the user; and

(d) means operatively associated with the decoding means, for determining a successful decoding of each symbol, and for non-manually terminating the reading of each symbol upon the determination of the successful decoding thereof.

* * *

11. A method of successively sensing and reading bar code symbols, each in its respective turn, comprising the steps of:

(a) generating a laser beam, and directing the same along a light path to each symbol;

(b) repetitively scanning the directed laser beam across each symbol for reflection therefrom;

(c) detecting the variable intensity of each scanned laser beam reflected from each symbol, and generating an electrical signal indicative of the detected intensity for each symbol;

(d) processing each electrical signal, and generating a processed electrical signal for each symbol;

(e) performing steps (a), (b), (c) and (d) in a light-weight, hand-held head, and normally supporting the same by a user in a normally non-contacting relationship with the symbols during reading thereof;

(f) decoding the processed signal for each symbol to be read;

(g) initiating [**42] reading of each symbol upon each manual actuation from one state [*1584] to another state of a trigger by the user; and

(h) determining a successful decoding of each symbol, and non-manually terminating the reading of each symbol upon the determination of the successful decoding thereof.

The '470 Patent

1. In a scanning system for reading bar code symbols, a scanning head comprising:

(a) a housing having an elongated body portion including a front region, a rear region, and an intermediate body region extending between the front and rear regions, and having side walls spaced transversely apart of each other by a predetermined width;

(b) light source means mounted within the housing, for generating an incident light beam;

(c) optic means mounted within the housing, for directing the incident beam along a light path towards a reference plane located exteriorly of the housing in the vicinity of the front region thereof, and towards a bar code symbol located in the vicinity of the reference plane to thereby generate a reflected light beam which is directed along a light path away from the reference plane and back towards the housing;

(d) scanning means mounted within the housing at the rear [**43] region thereof, for sweeping at least one of said beams over a field of view across the bar code symbol;

(e) sensor means mounted within the housing, for detecting the light intensity in the reflected beam over a field of view across the bar code symbol, and for generating an electrical signal indicative of the detected light intensity;

(f) signal processing means mounted within the housing, for processing the electrical signal to generate therefrom data descriptive of the bar code symbol; and

(g) window means mounted on the housing, and having a light-transmissive window at the rear region in close adjacent confronting relationship with the scanning means thereat, said window being configured and positioned in the light path of said at least one swept beam to permit the latter to pass through the window and unobstructedly travel exteriorly of and past the front and intermediate body regions of the housing,

> whereby the field of view of the swept beam is substantially independent of the predetermined width of the housing due to its exterior transmission outside of the front and intermediate body regions of the housing.

LEXSEE

In Re Dow Chemical Co.

No. 87-1406

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

837 F.2d 469; 1988 U.S. App. LEXIS 587; 5 U.S.P.Q.2D (BNA) 1529

January 25, 1988, Decided

PRIOR HISTORY: [**1]

Appealed from: United States Patent and Trademark Office Board of Patent Appeals and Interferences.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant challenged the order of the United States Patent and Trademark Office Board of Patent Appeals and Interferences, rejecting on reexamination all claims of appellant's patent application.

OVERVIEW: Appellant challenged the order of the appeals board rejecting all the claims of appellant's patent application, which based its decision on the contention that the claimed invention would have been obvious in terms of *35 U.S.C.S § 103.* Appellant argued that the board erred when it engaged in hindsight reconstruction of the claimed invention and combined prior art teachings when no reference showed or suggested that references should or could be combined successfully. The court found that the evidence as a whole did not support the board's conclusion that the claimed invention would have been obvious in terms of *35 U.S.C.S. § 103,* and that the board applied an incorrect "obvious to experiment" standard to its determination.

OUTCOME: The court reversed the board's rejection of appellant's patent application because it found that the evidence as a whole did not support the board's conclusion that the claimed invention would have been obvious, and the board applied an incorrect "obvious to experiment" standard to its determination.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN1] Recognition of need, and difficulties encountered by those skilled in the field, are classical indicia of unobviousness.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN2] The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN3] In determining whether a suggestion of obviousness can fairly be gleaned from the prior art, the full field of the invention must be considered, for the person of ordinary skill is charged with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN4] The skepticism of an expert, expressed before inventors proved him wrong, is entitled to fair evidentiary weight.

COUNSEL:

Douglas N. Deline, The Dow Chemical Co., argued for Appellant. With him on the brief was Bernd W. Sandt.

John H. Raubitschek, Associate Solicitor, Office of the Solicitor, argued for Appellee. With him on the brief were Joseph F. Nakamura, Solicitor and Fred E. McKelvey, Deputy Solicitor.

JUDGES:

Smith, Nies, and Newman, Circuit Judges.

OPINIONBY:

NEWMAN

OPINION:

[*470] NEWMAN, Circuit Judge.

Dow Chemical Company appeals the decisions of the United States Patent and Trademark Office Board of Patent Appeals and Interferences, No. 86-3426 (Feb. 25, 1987) and No. 662-81 (Mar. 25, 1986), together rejecting all the claims on reexamination of United States Patent No. *3,919,354* entitled "Impact Resistant Polymers of a Resinous Copolymer of an Alkenyl Aromatic Monomer and an Unsaturated Dicarboxylic Anhydride.". We reverse.

The Rejection

The invention is an impact resistant rubber-based resin having improved resistance to heat distortion. Claim 28, the broadest claim on appeal, is illustrative:

> 28. A polymer suitable for molding and extrusion, of substantially [**2] improved resistance to mechanical shock and impact, the polymer consisting essentially of the polymerization product of
>
> a. a monovinyl alkenyl aromatic monomer containing up to 12 carbon atoms and having the alkenyl group attached directly to the benzene nucleus, the alkenyl aromatic compound being present in a proportion of from about 65 to 95 parts by weight and from 35 to 5 parts by weight of an unsaturated dicarboxylic acid anhyride readily copolymerizable therewith, and
>
> b. from 5 to 35 parts by weight of a diene rubber per 100 parts of (a) plus (b), the rubber consisting essentially of 65 to 100 weight percent butadiene, or isoprene and up to 35 weight percent of an alkenyl aromatic hydrocarbon as the sole other monomer in the rubber, the rubber having a glass temperature not higher than 0 degrees C., the rubber being in the form of a plurality of particles having diameters within the range of 0.02 to 30 microns dispersed throughout a matrix of polymer of alkenyl aromatic monomer and the anhydride, at least a major portion of the rubber particles containing distinct occlusions of the polymer of (a), with the further limitation that
>
> the polymer of (a) is a nonequimolar [**3] random copolymer.

[*471] The preferred ingredients are styrene, maleic anhydride, and synthetic diene rubbers, and our discussion will be in these terms, as was the Board's.

The Board's decision that the claimed invention would have been obvious in terms of *35 U.S.C. § 103* was based on the combination of two references: a 1966 article by Molau and Keskkula entitled "Heterogeneous Polymer Systems IV. Mechanism of Rubber Particle Formation in Rubber-Modified Vinyl Polymers", and Baer U.S. Patent No. *2,971,939*. Also discussed were Farmer U.S. Patent No. *2,275,951* and a publication by Bacon and Farmer entitled "The Interaction of Maleic Anhydride with Rubber", although the Board stated that the rejection was sustainable without relying on either of these references.

The Prior Art

The Molau/Keskkula article shows the preparation of a resin having high impact strength by dissolving synthetic diene rubber in styrene and polymerizing the styrene. This reference teaches that phase inversion is necessary to the formation of these moldable, extrudable resins. Baer prepares nonequimolar random maleic anhydride-styrene copolymers by a technique [**4] whose salient feature is adding the maleic anhydride slowly to polymerizing styrene under controlled conditions.

Farmer shows the reaction among natural rubber, styrene, and maleic anhydride, and also states that maleic anhydride reacts directly with the rubber. The Bacon and Farmer article also shows the reaction of maleic anhydride with natural rubber. These products, according to Dow's evidence and as found by the Board, do not have a dispersed rubber phase containing occlusions, and are not moldable.

Dow argues that the Board has engaged in hindsight reconstruction of the claimed invention. To support its position Dow refers to several scientific publications and other references, in addition to those cited by the PTO, and evidence submitted by declaration and deposition.

The first group of references to which Dow refers shows the reaction of maleic anhydride with natural or synthetic rubbers. These references show both intermolecular and intramolecular reactions between maleic anhydride and the various rubbers, but not a grafted rubber, which is said by Dow to characterize its product. Additional references are cited by Dow to show that maleic anhydride is much more reactive [**5] with diene-type synthetic rubbers than with natural rubber, and that the reaction with the synthetic rubbers is difficult to control and the product is unpredictable.

Another reference cited by Dow, the *Encyclopedia of Science and Technology*, states the general rule, derived from experience with acrylonitrile, that copolymers with synthetic diene rubbers have elevated glass transition temperatures; Dow advises that this is a highly undesirable property for a high-impact strength resin.

Another series of references cited by Dow shows several known techniques of reacting styrene and maleic anhydride to prepare nonequimolar copolymers, all different from the technique shown in the Baer patent.

Analysis

The Board held that the claimed product results from the application of the Baer technique to a styrene-maleic anhydride polymer system which includes synthetic diene rubber, and that it would have been obvious to do that which these inventors did if one wanted to increase the heat stability of a known high impact styrene rubber resin.

The crux of Dow's argument is that no reference shows or suggests that these references should or could be combined successfully. Indeed, [**6] the Board agreed, stating that "it is not apparent from the evidence whether rubber and maleic anhydride would have been expected to react *in the process suggested by the combined disclosure of Molau and Baer* . . . ." (Emphasis in original).

Dow also points out, referring to the Keskkula evidence, that it was believed that these products could not be made by [*472] the mass polymerization techniques of the prior art. Dow asserts that no reference, including Baer, suggested that the Baer technique could produce the requisite phase inversion in a system containing diene rubber, and could produce a diene-rubber containing resin that could be molded and had the other desired high-impact and thermal properties.

Dow refers to the Farmer patent, cited by the examiner and the Board, which shows that the reaction of styrene, maleic anhydride, and natural rubber forms a product that is unsuitable as a molding resin. Dow argues that Farmer leads away from the Dow invention, in that Farmer obtains precisely the "runaway" reaction, and undesirable product, that Keskkula believed was characteristic of reactions involving styrene, maleic anhydride, and rubbers. Dow points to Dr. Keskkula's [**7] Report to Dow management, written in 1966 at about the time the present invention was made, pointing out the many problems in attempting to produce the three-component product that these inventors later succeeded in producing.

In response, the Commissioner argues that even though an expert polymer scientist, Dr. Keskkula, "personally may have been surprised by the invention at the time it was made, it does not necessarily follow that the invention would have been unobvious to one of ordinary skill in the art." The Commissioner suggests that one less encumbered by knowledge of the need for phase inversion, as described in the Molau/Keskkula article, might have achieved the Dow product by combining the references in the way suggested by the Commissioner. Reflecting on this theory of invention, we observe that such a person did not do so, despite the decades of experimentation with these components, and the recognition of need, as evidenced by the many references cited by both sides. *See In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984).* [**8]

The Board held that Dow's statement in the patent specification that it was known that styrene/maleic anhydride copolymers had improved heat resistance as compared with styrene rubbers, made it prima facie obvious to combine these three components. Indeed, the record shows that such combinations had previously been made, in various ways, but without producing the product here desired. That there were other attempts, and various combinations and procedures tried in the past, does not render obvious the later successful one. The PTO's reliance on Dow's "admission" of longfelt need as prima facie evidence of obviousness is contrary to logic as well as law. [HN1] Recognition of need, and difficulties encountered by those skilled in the field, are classical indicia of unobviousness. *Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966); Custom Accessories v. Jeffrey-Allan Industries, 807 F.2d 955, 960, 1 USPQ2d 1196, 1199 (Fed. Cir. 1986).* Further, a patent applicant's statement of the purpose of the work is not prior [**9] art.

The Board thus concluded that although one would not know in advance whether the Baer technique would work at all in the presence of diene rubber, or produce a moldable high-impact product, if it did succeed it would have been obvious. The Board criticized Keskkula's evidence for not stating whether, after these inventors proposed the procedure here at issue, Keskkula would have expected the maleic anhydride to react preferentially with the diene rubber or with the styrene and to what effect on the impact properties of the product. The PTO argues that unless the prior art is shown to have led one of ordinary skill to expect the Baer technique to fail, the applicant's burden is not met. This is not the criterion. That these inventors eventually succeeded when they and others had failed does not mean that they or their colleagues must have expected each new idea to fail. Most technological advance is the fruit of methodical, persistent investigation, as is recognized in *35 U.S.C. § 103* ("Patentability shall not be negatived by the manner in which the invention was made").

[*473] [HN2] [**10] The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. *See Burlington Industries v. Quigg, 822 F.2d 1581, 1583, 3 USPQ2d 1436, 1438 (Fed. Cir. 1987); In re Hedges, 783 F.2d 1038, 1041, 228 USPQ 685, 687 (Fed. Cir. 1986); Orthopedic Equipment Co. v. United States, 702 F.2d 1005, 1013, 217 USPQ 193, 200 (Fed. Cir. 1983); In re Rinehart, 531 F.2d 1048, 1053-54, 189 USPQ 143, 148 (CCPA 1976).* Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure.

[HN3] In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered; for the person of ordinary skill is charged with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention. The [**11] Commissioner argues that since the PTO is no longer relying on Farmer or the Bacon and Farmer article, the applicant is creating a "straw man". It is indeed pertinent that these references teach against the present invention. Evidence that supports, rather than negates, patentability must be fairly considered.

The PTO presents, in essence, an "obvious to experiment" standard for obviousness. However, selective hindsight is no more applicable to the design of experiments than it is to the combination of prior art teachings. There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure. *Interconnect Planning Corporation v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985).* Of the many scientific publications cited by both Dow and the PTO, none suggests that any process could be used successfully in this three-component system, to produce this product having the desired properties. [HN4] The skepticism of an expert, expressed before these inventors proved him wrong, is entitled to fair [**12] evidentiary weight, *see In re Piasecki, 745 F.2d 1468, 1475, 223 USPQ 785, 790 (Fed. Cir. 1984); In re Zeidler, 682 F.2d 961, 966, 215 USPQ 490, 494 (CCPA 1982),* as are the five to six years of research that preceded the claimed invention. The evidence as a whole does not support the PTO's conclusion that the claimed invention would have been obvious in terms of *35 U.S.C. § 103.*

REVERSED.

LEXSEE

IN RE PATRICK H. O'FARRELL, BARRY A. POLISKY and DAVID H. GELFAND

No. 87-1486

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

853 F.2d 894; 1988 U.S. App. LEXIS 10951; 7 U.S.P.Q.2D (BNA) 1673

August 10, 1988, Decided

PRIOR HISTORY: [**1]

Appealed from: U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellants sought review of the decision of U.S. Patent and Trademark Office Board of Patent Appeals and Interferences rejecting appellants' application under *35 U.S.C.S. § 103* because the claimed invention was obvious at the time the invention was made in view of a published paper by two of the coinventors.

OVERVIEW: Appellants alleged that at the time their article was published there was significant unpredictability in the field of molecular biology so that the article would not have rendered the claimed method of translating heterologous DNA in bacteria obvious to one of ordinary skill in the art. In the alternative, appellants argued that the rejection was founded on the impermissible "obvious to try" standard. The court disagreed, holding that in light of the article, the claimed invention would have been obvious within the meaning of *35 U.S.C.S. § 103*. The article contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful. Appellants foreclosed themselves from obtaining a patent because they published their pioneering studies more than a year before applying for a patent.

OUTCOME: The decision rejecting appellants' patent application was affirmed because the claimed invention was obvious in light of the published paper by two of the three co-inventors prior to filing their patent application.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN1] See *35 U.S.C.S. § 103*.

Civil Procedure > Trials > Bench TrialsPatent Law > Nonobviousness > Tests & Proof of Obviousness
[HN2] Obviousness under *35 U.S.C.S. § 103* is a question of law.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN3] An analysis of obviousness must be based on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any.

Patent Law > Nonobviousness > Tests & Proof of Obviousness
[HN4] Keeping the four statutory factors in mind and considering all of the evidence, the court must determine the correctness of the board's legal determination that the claimed invention as a whole would have been obvious to a person having ordinary skill in the art at the time the invention was made.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN5] Obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious.

COUNSEL:

J. Bruce McCubbrey, Fitch, Even, Tabin & Flannery, of San Francisco, California, argued for Appellant. Virginia H. Meyer, Fitch, Even, Tabin & Flannery, of San Francisco, California, was on the brief for Appellant.

Harris A. Pitlick, Associate Solicitor, of Arlington, Virginia, argued for Appellee. With him on the brief were Joseph F. Nakamura, Solicitor and Fred E. McKelvey, Deputy Solicitor.

JUDGES:

Markey, Chief Judge, Rich and Nies, Circuit Judges.

OPINIONBY:

RICH

OPINION:

[*895] RICH, Circuit Judge.

This appeal is from the decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences (board) affirming the patent examiner's final rejection of patent application Serial No. 180,424, entitled "Method and Hybrid Vector for Regulating Translation of Heterologous DNA in Bacteria." The application was rejected under *35 U.S.C. § 103* on the ground that the claimed invention would have been obvious at the time the invention was made in view of a published paper by two of the three coinventors, and a publication by Bahl, [**2] Marians & Wu, 1 *Gene* 81 (1976) (Bahl). We affirm.

The claimed invention is from the developing new field of genetic engineering. A broad claim on appeal reads:

> Claim 1. A method for producing a predetermined protein in a stable form in a transformed host species of bacteria comprising, providing a cloning vector which includes at least a substantial portion of a gene which is indigenous to the host species of bacteria and is functionally transcribed and translated in that species, said substantial portion of said indigenous gene further including the regulatory DNA sequences for RNA synthesis and protein synthesis but lacking the normal gene termination signal, and linking a natural or synthetic heterologous gene encoding said predetermined protein to said indigenous gene portion at its distal end, said heterologous gene being in proper orientation and having codons arranged in the same reading frame as the codons of said indigenous gene portion so that readthrough can occur from said indigenous gene portion into said heterologous gene in the same reading frame, said heterologous gene portion further containing sufficient DNA sequences to result in expression of a fused [**3] protein having sufficient size so as to confer stability on said predetermined protein when said vector is used to transform said host species of bacteria.

Illustrative embodiments are defined in more specific claims. For example:

> Claim 2. A method for producing a predetermined protein in a stable form in a transformed host species of bacteria, comprising, providing an *E. coli* plasmid having an operator, a promoter, a site for the initiation of translation, and at least a substantial portion of the beta-galactosidase gene of the *E. coli* lactose operon, said substantial portion of said beta-galactosidase gene being under the control of said operator, promoter and site for initiation of translation, said substantial portion of said beta-galactosidase gene lacking the normal gene termination signal, and linking a heterologous gene encoding said predetermined protein to said beta-galactosidase gene portion at its distal end, said heterologous gene being in proper orientation and having codons arranged in the same reading frame as the codons of the said beta-galactosidase gene portion so that readthrough can occur

from said beta-galactosidase gene portion into said [**4] heterologous gene in the same reading frame, said heterologous gene portion further containing sufficient DNA sequences to result in expression of a fused protein having sufficient size so as to confer stability on said predetermined protein when said vector is used to transform said host species of bacteria.

Claim 3. The method of Claim 2 wherein said *E. coli* plasmid comprises the plasmid designated pBGP120.

Although the terms in these claims would be familiar to those of ordinary skill in genetic engineering, they employ a bewildering vocabulary new to those who are not versed in molecular biology. An understanding of the science and technology on which these claims are based is essential before one can analyze and explain whether the claimed invention would have been obvious in light of the prior art.

I. *Background* n1

n1 Basic background information about molecular biology and genetic engineering, can be found in Alberts, Bray, Lewis, Raff, Roberts & Watson, *The Molecular Biology of the Cell*, 1-253, 385-481 (1983) [hereinafter *The Cell*]; Watson, Hopkins, Roberts, Steitz & Weiner, *The Molecular Biology of the Gene*, Vol. 1 (4th ed., 1987) 3-502 [hereinafter *The Gene*]. These standard textbooks were used to supplement the information in the glossary supplied by appellants. The description here is necessarily simplified and omits important facts and concepts that are not necessary for the analysis of this case.

[**5]

Proteins are biological molecules of enormous importance. Proteins include enzymes [*896] that catalyze biochemical reactions, major structural materials of the animal body, and many hormones. Numerous patents and applications for patents in the field of biotechnology involve specific proteins or methods for making and using proteins. Many valuable proteins occur in nature only in minute quantities, or are difficult to purify from natural sources. Therefore, a goal of many biotechnology projects, including appellants' claimed invention, is to devise methods to synthesize useful quantities of specific proteins by controlling the mechanism by which living cells make proteins.

The basic organization of all proteins is the same. Proteins are large polymeric molecules consisting of chains of smaller building blocks, called *amino acids*, that are linked together covalently. n2 The chemical bonds linking amino acids together are called *peptide* bonds, so proteins are also called *polypeptides*. n3 It is the exact sequence in which the amino acids are strung together in a polypeptide chain that determines the identity of a protein and its chemical characteristics. n4 Although [**6] there are only 20 amino acids, they are strung together in different orders to produce the hundreds of thousands of proteins found in nature.

n2 There are twenty amino acids: alanine, valine, leucine, isoleucine, proline, phenylalanine, methionine, tryptophan, glycine, asparagine, glutamine, cysteine, serine, threonine, tyrosine, aspartic acid, glutamic acid, lysine, arginine, and histidine.

n3 Proteins are often loosely called *peptides*, but technically proteins are only the larger peptides with chains of at least 50 amino acids, and more typically hundreds of amino acids. Some proteins consist of several polypeptide chains bound together covalently or noncovalently. The term "peptide" is broader than "protein" and also includes small chains of amino acids linked by peptide bonds, some as small as two amino acids. Certain small peptides have commercial or medical significance.

n4 Polypeptide chains fold up into complex 3-dimensional shapes. It is the shape that actually determines many chemical properties of the protein. However, the configuration of a protein molecule is determined by its amino acid sequence. *The Cell* at 111-12; *The Gene* at 50-54.

[**7]

To make a protein molecule, a cell needs information about the sequence in which the amino acids must be assembled. The cell uses a long polymeric molecule, DNA (deoxyriboneucleic acid), to store this information. The subunits of the DNA chain are called *nucleotides*. A nucleotide consists of a nitrogen-containing ring compound (called a *base*) linked to a 5-carbon sugar that has a phosphate group attached. n5 DNA is composed of only four nucleotides. They differ from each other in the base region of the molecule. The four bases of these subunits are adenine, guanine, cytosine, and thymine (abbreviated respectively as A, G, C and T). The sequence of these bases along the DNA molecule specifies which amino acids will be inserted in sequence into the polypeptide chain of a protein.

n5 The sugar in DNA is deoxyribose, while the sugar in RNA, *infra*, is ribose. The sugar and phosphate groups are linked covalently to those of adjacent nucleotides to form the backbone of the long unbranched DNA molecule. The bases project from the chain, and serve as the "alphabet" of the genetic code.

DNA molecules actually consist of two chains tightly entwined as a double helix. The chains are not identical but instead are complementary: each A on one chain is paired with a T on the other chain, and each C has a corresponding G. The chains are held together by noncovalent bonds between these complementary bases. This double helical structure plays an essential role in the replication of DNA and the transmission of genetic information. *See generally The Cell* at 98-106; *The Gene* at 65-79. However, the information of only one strand is used for directing protein synthesis, and it is not necessary to discuss the implication of the double-stranded structure of DNA here. RNA molecules, *infra*, are single stranded.

[**8]

DNA molecules do not participate directly in the synthesis of proteins. DNA acts as a permanent "blueprint" of all of the [*897] genetic information in the cell, and exists mainly in extremely long strands (called *chromosomes*) containing information coding for the sequences of many proteins, most of which are not being synthesized at any particular moment. The region of DNA on the chromosome that codes for the sequence of a single polypeptide is called a *gene*. n6 In order to *express* a gene (the process whereby the information in a gene is used to synthesize new protein), a copy of the gene is first made as a molecule of RNA (ribonucleic acid).

n6 Chromosomes also contain regions of DNA that are not part of genes, i.e., do not code for the sequence of amino acids in proteins. These include sections of DNA adjacent to genes that are involved in the control of transcription, *infra*, and regions of unknown function.

RNA is a molecule that closely resembles DNA. It differs, however, in that [**9] it contains a different sugar (ribose instead of deoxyribose) and the base thymine (T) of DNA is replaced in RNA by the structurally similar base, uracil (U). Making an RNA copy of DNA is called *transcription*. The transcribed RNA copy contains sequences of A, U, C, and G that carry the same information as the sequence of A, T, C, and G in the DNA. That RNA molecule, called *messenger RNA*, then moves to a location in the cell where proteins are synthesized.

The code whereby a sequence of nucleotides along an RNA molecule is translated into a sequence of amino acids in a protein (i.e., the "genetic code") is based on serially reading groups of three adjacent nucleotides. Each combination of three adjacent nucleotides, called a *codon*, specifies a particular amino acid. For example, the codon U-G-G in a messenger RNA molecule specifies that there will be a tryptophan molecule in the corresponding location in the corresponding polypeptide. The four bases A, G, C and U can be combined as triplets in 64 different ways, but there are only 20 amino acids to be coded. Thus, most amino acids are coded for by more than one codon. For example, both U-A-U and U-A-C code for tyrosine, [**10] and there are six different codons that code for leucine. There are also three codons that do not code for any amino acid (namely, U-A-A, U-G-A, and U-A-G). Like periods at the end of a sentence, these sequences signal the end of the polypeptide chain, and they are therefore called *stop codons*.

The cellular machinery involved in synthesizing proteins is quite complicated, and centers around large structures called *ribosomes* that bind to the messenger RNA. The ribosomes and associated molecules "read" the information in the messenger RNA molecule, literally shifting along the strand of RNA three nucleotides at a time, adding the amino acid specified by that codon to a growing polypeptide chain that is also attached to the ribosome. When a stop codon is reached, the polypeptide chain is complete and detaches from the ribosome.

The conversion of the information from a sequence of codons in an RNA molecule into the sequence of amino acids in a newly synthesized polypeptide is called *translation*. A messenger RNA molecule is typically reused to make many copies of the same protein. Synthesis of a protein is usually terminated by destroying the messenger RNA. (The information [**11] for making more of that protein remains stored in DNA in the chromosomes.)

The translation of messenger RNA begins at a specific sequence of nucleotides that bind the RNA to the ribosome and specify which is the first codon that is to be translated. Translation then proceeds by reading nucleotides, three at a time, until a stop codon is reached. If some error were to occur that shifts the frame in which the nucleotides are read by one or two nucleotides, all of

the codons after this shift would be misread. For example, the sequence of codons [. . . *C-U-C-A-G-C-G-U-U-A-C-C-A*. . .] codes for the chain of amino acids [. .. leucine-serine-valine-threonine-. . .]. If the reading of these groups of three nucleotides is displaced by one nucleotide, such as [. . . *C-U-C-A-G-C-G-U-U-A-C-C-A* . . .], the resulting peptide chain would consist of [*898] [. . . serine-alanine-leucine-proline. . .]. This would be an entirely different peptide, and most probably an undesirable and useless one. Synthesis of a particular protein requires that the correct register or *reading frame* be maintained as the codons in the RNA are translated.

The function of messenger RNA is to carry [**12] genetic information (transcribed from DNA) to the protein synthetic machinery of a cell where its information is translated into the amino acid sequence of a protein. However, some kinds of RNA have other roles. For example, ribosomes contain several large strands of RNA that serve a structural function (*ribosomal RNA*). Chromosomes contain regions of DNA that code for the nucleotide sequences of structural RNAs and these sequences are transcribed to manufacture those RNAs. The DNA sequences coding for structural RNAs are still called genes even though the nucleotide sequence of the structural RNA is never translated into protein.

Man, other animals, plants, protozoa, and yeast are *eucaryotic* (or eukaryotic) organisms: their DNA is packaged in chromosomes in a special compartment of the cell, the nucleus. Bacteria (*procaryotic* or prokaryotic organisms) have a different organization. Their DNA, usually a circular loop, is not contained in any specialized compartment. Despite the incredible differences between them, all organisms, whether eucaryote or procaryote, whether man or mouse or lowly bacterium, use the same molecular rules to make proteins under the control of genes. [**13] In all organisms, codons in DNA are transcribed into codons in RNA which is translated on ribosomes into polypeptides according to the same genetic code. Thus, if a gene from a man is transferred into a bacterium, the bacterium can manufacture the human protein. Since most commercially valuable proteins come from man or other eucaryotes while bacteria are essentially little biochemical factories that can be grown in huge quantities, one strategy for manufacturing a desired protein (for example, insulin) is to transfer the gene coding for the protein from the eucaryotic cell where the gene normally occurs into a bacterium.

Bacteria containing genes from a foreign source (*heterologous* genes) integrated into their own genetic makeup are said to be *transformed*. When transformed bacteria grow and divide, the inserted heterologous genes, like all the other genes that are normally present in the bacterium (*indigenous* genes), are replicated and passed on to succeeding generations. One can produce large quantities of transformed bacteria that contain transplanted heterologous genes. The process of making large quantities of identical copies of a gene (or other fragment of DNA) [**14] by introducing it into procaryotic cells and then growing those cells is called *cloning* the gene. After growing sufficient quantities of the transformed bacteria, the biotechnologist must induce the transformed bacteria to *express* the cloned gene and make useful quantities of the protein. This is the purpose of the claimed invention.

In order to make a selected protein by expressing its cloned gene in bacteria, several technical hurdles must be overcome. First the gene coding for the specific protein must be isolated for cloning. This is a formidable task, but recombinant DNA technology has armed the genetic engineer with a variety of techniques to accomplish it. n7 Next the isolated gene must be introduced into the host bacterium. This can be done by incorporating the gene into a cloning vector. A *cloning vector* is a piece of DNA that can be introduced into bacteria and will then replicate itself as the bacterial cells grow and divide. Bacteriophage (viruses that infect bacteria) can be used as cloning vectors, but plasmids were the type used by appellants. A *plasmid* is a small circular loop of DNA found in bacteria, separate from the chromosome, that replicates [**15] like a chromosome. It is like a tiny auxilliary chromosome containing only a few genes. Because of their small size, plasmids are convenient for the molecular biologist to isolate and work with. Recombinant DNA technology can be used to modify plasmids by splicing in cloned eucaryotic [*899] genes and other useful segments of DNA containing control sequences. Short pieces of DNA can even be designed to have desired nucleotide sequences, synthesized chemically, and spliced into the plasmid. One use of such chemically synthesized linkers is to insure that the inserted gene has the same reading frame as the rest of the plasmid; this is a teaching of the Bahl reference cited against appellants. A plasmid constructed by the molecular geneticist can be inserted into bacteria, where it replicates as the bacteria grow.

n7 *See The Cell* at 185-194; *The Gene* at 208-10.

Even after a cloned heterologous gene has been successfully inserted into bacteria using a plasmid as a cloning vector, and replicates as [**16] the bacteria grow, there is no guarantee that the gene will be expressed, i.e., transcribed and translated into protein. A bacterium such as *E. coli* (the species of bacterium used

by appellants) has genes for several thousand proteins. At any given moment many of those genes are not expressed at all. The genetic engineer needs a method to "turn on" the cloned gene and force it to be expressed. This is the problem appellants worked to solve.

II. *Prior art*

Appellants sought to control the expression of cloned heterologous genes inserted into bacteria. They reported the results of their early efforts in a publication, the three authors of which included two of the three coinventor-appellants (the Polisky reference n8), that is undisputed prior art against them. Their strategy was to link the foreign gene to a highly regulated indigenous gene. Turning on expression of the indigenous gene by normal control mechanisms of the host would cause expression of the linked heterologous gene.

n8 Polisky, Bishop & Gelfand, *A plasmid cloning vehicle allowing regulated expression of eukaryotic DNA in bacteria*, 73 Proc. Nat'l Acad. Sci. USA 3900 (1976).

[**17]

As a controllable indigenous gene, the researchers chose a gene in the bacterium *E. coli* that makes beta-galactosidase. *Beta-galactosidase* is an enzyme needed to digest the sugar, lactose (milk sugar). When *E. coli* grows in a medium that contains no lactose, it does not make beta-galactosidase. If lactose is added to the medium, the gene coding for beta-galactosidase is expressed. The bacterial cell makes beta-galactosidase and is then able to use lactose as a food source. When lactose is no longer available, the cell again stops expressing the gene for beta-galactosidase.

The molecular mechanisms through which the presence of lactose turns on expression of the beta-galactosidase gene has been studied in detail, and is one of the best understood examples of how gene expression is regulated on the molecular level. The beta-galactosidase gene is controlled by segments of DNA adjacent to the gene. These *regulatory DNA sequences* (the general term used in Claim 1) include the *operator* and *promoter* sequences (specified in Claim 2). n9 The researchers constructed a plasmid containing the beta-galactosidase gene with its operator and promoter. This gene (with its [**18] regulatory sequences) was removed from the chromosome of *E. coli* where it is normally found and was transplanted to a plasmid that could be conveniently manipulated.

n9 The *promoter* is a sequence of nucleotides where the enzyme that synthesizes RNA, *RNA polymerase*, attaches to the DNA to start the transcription of the beta-galactosidase gene. The *operator* is an overlapping DNA sequence that binds a small protein present in the cell, the lactose repressor protein. The lactose repressor protein binds to the operator and physically blocks the RNA polymerase from properly attaching to the promoter so that transcription cannot proceed. Lactose molecules interact with the lactose repressor protein and cause it to change its shape; after this change in shape it moves out of the way and no longer prevents the RNA polymerase from binding to the promoter. Messenger RNA coding for beta-galactosidase can then be transcribed. *See generally The Cell* at 438-39; *The Gene* at 474-80.

Restriction endonucleases [**19] are useful tools in genetic engineering. These enzymes cut strands of DNA, but only at places where a specific sequence of nucleotides is present. For example, one restriction endonuclease, called *EcoRI*, cuts DNA only at sites where the nucleotide sequence is [. . .-G-A-A-T-T-C-. . .]. With restriction [*900] enzymes the genetic engineer can cut a strand of DNA at very specific sites into just a few pieces. With the help of "repair" enzymes, other pieces of DNA can be spliced onto the cut ends. The investigators found that the plasmid which they had constructed contained only two sequences that were cut by EcoRI. They were able to eliminate one of these sites that was unwanted. They were then left with a plasmid containing the beta-galactosidase gene with its regulatory sequences, and a single EcoRI site that was within the beta-galactosidase gene and close to its stop codon. They named this plasmid that they had constructed pBGP120.

The next step was to cut the plasmid open at its EcoRI site and insert a heterologous gene from another organism. The particular heterologous gene they chose to splice in was a segment of DNA from a frog that coded for ribosomal RNA. The frog [**20] gene was chosen as a test gene for reasons of convenience and availability. The new plasmid created by inserting the frog gene was similar to pBGP120, but its beta-galactosidase gene was incomplete. Some codons including the stop codon were missing from its end, which instead continued on with the sequence of the frog ribosomal RNA gene. The investigators named this new plasmid pBGP123. They inserted this plasmid back into *E. coli* and grew sufficient quantities for study. They then fed the *E. coli* with lactose. As they had intended, the lactose turned on transcription of the beta-galactosidase gene in the plasmid. RNA polymerase moved along the plasmid

producing a strange new kind of RNA: Each long strand of RNA first contained codons for the messenger RNA for beta-galactosidase and then continued without interruption with the codons for the frog ribosomal RNA. Thus, there was *readthrough* transcription in which the RNA polymerase first transcribed the indigenous (beta-galactosidase) gene and then "read through," i.e., continued into and through the adjacent heterologous (frog ribosomal RNA) gene. Although the RNA produced was a hybrid, it nevertheless contained a nucleotide [**21] sequence dictated by DNA from a frog. The researchers had achieved the first controlled transcription of an animal gene inside a bacterium.

The researchers had used a gene coding for a ribosomal RNA as their heterologous test gene. Ribosomal RNA is not normally translated into protein. Nevertheless, they were obviously interested in using their approach to make heterologous proteins in bacteria. They therefore examined the beta-galactosidase made by their transformed bacteria. Patrick O'Farrell, who was not a coauthor of the Polisky paper but was to become a coinventor in the patent application, joined as a collaborator. They found that beta-galactosidase from the transformed bacteria had a higher molecular weight than was normal. They concluded that the bacteria must have used their strange new hybrid RNA like any other messenger RNA and translated it into protein. When the machinery of protein synthesis reached the premature end of the sequence coding for beta-galactosidase it continued right on, three nucleotides at a time, adding whatever amino acid was coded for by those nucleotides, until a triplet was reached with the sequence of a stop codon. The resulting polypeptide chains [**22] had more amino acids than normal beta-galactosidase, and thus a higher molecular weight. The researchers published their preliminary results in the Polisky article. They wrote:

> If the normal translational stop signals for [beta]-galactosidase are missing in pBGP120, in-phase translational readthrough into adjacent inserted sequences might occur, resulting in a significant increase in the size of the [beta]-galactosidase polypeptide subunit. In fact, we have recently observed that induced cultures of pBGP123 contain elevated levels of [beta]-galactosidase of higher subunit molecular weight than wild-type enzyme (P. O'Farrell, unpublished experiments). We believe this increase results from translation of *Xenopus* [frog] RNA sequences covalently linked to [messenger] RNA for [beta]-galactosidase, resulting in a fused polypeptide.

Polisky at 3904.

Since ribosomal RNA is never translated in normal cells, the polypeptide chain produced [*901] by translating that chain was not a naturally occuring, identified protein. The authors of the Polisky paper explicitly pointed out that if one were to insert a heterologous gene coding for a protein into their [**23] plasmid, it should produce a "fused protein" consisting of a polypeptide made of beta-galactosidase plus the protein coded for by the inserted gene, joined by a peptide bond into a single continuous polypeptide chain:

> It would be interesting to examine the expression of a normally translated eukaryotic sequence in pBGP120. If an inserted sequence contains a ribosome binding site that can be utilized in bacteria, production of high levels of a readthrough transcript might allow for extensive translation of a functional eukaryotic polypeptide. In the absence of an independent ribosome binding site, the eukaryotic sequence would be translated to yield a peptide covalently linked to [beta]-galactosidase. The extent of readthrough translation under *lac* control will depend on the number of translatable codons between the EcoRI site and the first in-phase nonsense [i.e., stop] codon in the inserted sequence.

Id.

III. *The Claimed Invention*

Referring back to Claims 1 through 3, it can be seen that virtually everything in the claims was present in the prior art Polisky article. The main difference is that in Polisky the heterologous gene was a gene [**24] for ribosomal RNA while the claimed invention substitutes a gene coding for a predetermined protein. Ribosomal RNA gene is not normally translated into protein, so expression of the heterologous gene was studied mainly in terms of transcription into RNA. Nevertheless, Polisky mentioned preliminary evidence that the transcript of the ribosomal RNA gene was translated into protein. Polisky further predicted that if a gene that codes for a protein were to be substituted for the ribosomal RNA gene, "a readthrough transcript might allow for extensive translation of a functional eukaryotic polypeptide." Thus,

the prior art explicitly suggested the substitution that is the difference between the claimed invention and the prior art, and presented preliminary evidence suggesting that the method could be used to make proteins.

Appellants reduced their invention to practice some time in 1976 and reported their results in a paper that was published in 1978. n10 During 1977 they communicated their results to another group of researchers who used the readthrough translation approach to achieve the first synthesis of a human protein in bacteria. n11 Appellants filed an application to patent their [**25] invention on August 9, 1978, of which the application on appeal is a division.

n10 O'Farrell, Polisky & Gelfand, *Regulated expression by readthrough translation from a plasmid-encoded beta-galactosidase*, 134 J. Bacteriol. 645 (1978). The heterologous genes expressed in these studies were not predetermined, but were instead unidentified genes of unknown origin. The authors speculated that they were probably genes from *E. coli* that were contaminants in the source of beta-galactosidase genes. *Id.* at 648.

n11 Itakura, Hirose, Crea, Riggs, Heynecker, Bolivar & Boyer, *Expression in Escherichia coli of a chemically synthesized gene for the hormone somatostatin*, 198 Science 1056 (1977). A pioneering accomplishment of the Itakura group is that the gene was not from a human source, but instead was entirely synthesized in the laboratory using chemical methods. It is not clear whether the appellants communicated only the results reported in the Polisky publication or whether they communicated the complete claimed invention.

[**26]

IV. *The Obviousness Rejection*

The application was rejected under [HN1] *35 U.S.C. § 103*. The position of the examiner and the Board is, simply, that so much of the appellant's method was revealed in the Polisky reference that making a protein by substituting its gene for the ribosomal RNA gene in Polisky (as suggested by Polisky) would have been obvious to one of ordinary skill in the art at the time that the invention was made.

The claims specify that the heterologous gene should be inserted into the plasmid in the same orientation and with the same reading frame as the preceding portion of [*902] the indigenous gene. In view of this limitation, the § 103 rejection was based either on Polisky alone (supplemented by the fact that the importance of orientation and reading frame was well known in the prior art) or in combination with the Bahl reference which describes a general method for inserting a piece of chemically synthesized DNA into a plasmid. Bahl teaches that this technique could be used to shift the sequence of DNA inserted into a plasmid into the proper [**27] reading frame.

Appellants argue that at the time the Polisky article was published, there was significant unpredictability in the field of molecular biology so that the Polisky article would not have rendered the claimed method obvious to one of ordinary skill in the art. Even though there was speculation in the article that genes coding for proteins could be substituted for the ribosomal RNA gene and would be expressed as readthrough translation into the protein, this had never been done. Appellants say that it was not yet certain whether a heterologous protein could actually be produced in bacteria, and if it could, whether additional mechanisms or methods would be required. They contend that without such certainty the predictions in the Polisky paper, which hindsight now shows to have been correct, were merely invitations to those skilled in the art to try to make the claimed invention. They argue that the rejection amounts to the application of a standard of "obvious to try" to the field of molecular biology, a standard which this court and its predecessors have repeatedly rejected as improper grounds for a § 103 rejection. *E.g., In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988);* [**28] *In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 379 (Fed. Cir. 1986); In re Antonie, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977).*

[HN2] Obviousness under § 103 is a question of law. *Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597* (Fed. Cir.), *cert. denied, 481 U.S. 1052, 107 S. Ct. 2187, 95 L. Ed. 2d 843 (1987).* [HN3] An analysis of obviousness must be based on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any. *Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966). See, e.g., Custom Accessories, Inc. v. Jeffrey-Allan Indus., 807 F.2d 955, 958, 1 USPQ2d 1196, 1197 (Fed. Cir. 1986).* [**29] The scope and content of the prior art and the differences between the prior art and the claimed invention have been examined in sections II and III, *supra*. Appellants say that in 1976 those of ordinary skill in the arts of molecular biology and recombinant DNA

technology were research scientists who had "extraordinary skill in relevant arts" and "were among the brightest biologists in the world." Objective evidence of nonobviousness was not argued.

[HN4] With the statutory factors as expounded by *Graham* in mind and considering all of the evidence, this court must determine the correctness of the board's legal determination that the claimed invention as a whole would have been obvious to a person having ordinary skill in the art at the time the invention was made. We agree with the board that appellant's claimed invention would have been obvious in light of the Polisky reference alone or in combination with Bahl within the meaning of § 103. Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed [**30] invention, and evidence suggesting that it would be successful.

Appellants argue that after the publication of Polisky, successful synthesis of protein was still uncertain. They belittle the predictive value of the observation that expression of the transcribed RNA in Polisky produced beta-galactosidase with a greater than normal molecular weight, arguing that since ribosomal RNA is not normally translated, the polypeptide chains that were added to the end of the beta-galactosidase [*903] were "junk" or "nonsense" proteins. This characterization ignores the clear implications of the reported observations. The Polisky study directly proved that a readthrough transcript messenger RNA had been produced. The preliminary observation showed that this messenger RNA was read and used for successful translation. It was well known in the art that ribosomal RNA was made of the same nucleotides as messenger RNA, that any sequence of nucleotides could be read in groups of three as codons, and that reading these codons should specify a polypeptide chain that would elongate until a stop codon was encountered. The preliminary observations thus showed that codons beyond the end of the beta-galactosidase [**31] gene were being translated into peptide chains. This would reasonably suggest to one skilled in the art that if the codons inserted beyond the end of the beta-galactosidase gene coded for a "predetermined protein," that protein would be produced. In other words, it would have been obvious and reasonable to conclude from the observation reported in Polisky that since nonsense RNA produced nonsense polypeptides, if meaningful RNA was inserted instead of ribosomal RNA, useful protein would be the result. The relative shortness of the added chains is also not a source of uncertainty, since one skilled in the art would have known that a random sequence of nucleotides would produce a stop codon before the chain got too long. n12

n12 The patent application indicates that chains as long as 60 amino acids were added, which is hardly a trivial length of polypeptide.

Appellants complain that since predetermined proteins had not yet been produced in transformed bacteria, there was uncertainty as to whether this could [**32] be done, and that the rejection is thus founded on an impermissible "obvious to try" standard. It is true that this court and its predecessors have repeatedly emphasized that "obvious to try" is not the standard under § 103. However, the meaning of this maxim is sometimes lost. Any invention that would in fact have been obvious under § 103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless nonobvious?

The admonition that "obvious to try" is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. *E.g., In re Geiger, 815 F.2d at 688, 2 USPQ2d at 1278; Novo Industri A/S v. Travenol Laboratories, Inc., 677 F.2d 1202, 1208, 215 USPQ 412, 417 (7th Cir. 1982); In re Yates, 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981);* [**33] *In re Antonie, 559 F.2d at 621, 195 USPQ at 8-9.* In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1986), cert. denied, 480 U.S. 947, 107 S. Ct. 1606, 94 L. Ed. 2d 792 (1987); In re Tomlinson, 53 C.C.P.A. 1421, 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966).* Neither of these situations applies here.

[HN5] Obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for [**34] showing that the invention, although apparently obvious, was in law nonobvious. *In re Merck & Co., 800 F.2d at 1098, 231 USPQ at 380; Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1461,* [*904] *221 USPQ 481, 488*

(Fed. Cir. 1984); In re Papesch, 50 C.C.P.A. 1084, 315 F.2d 381, 386-87, 137 USPQ 43, 47-48 (CCPA 1963). For obviousness under § 103, all that is required is a reasonable expectation of success. *In re Longi, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985); In re Clinton, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976).* The information in the Polisky reference, when combined with the Bahl reference provided such a reasonable expectation of success.

Appellants published their pioneering studies of the expression of frog ribosomal RNA genes in bacteria more than a year before they applied for a patent. After providing virtually all of their method to the public without applying for a patent within a year, they foreclosed themselves from obtaining a patent on a method that would have been obvious from their publication to those of ordinary [**35] skill in the art, with or without the disclosures of other prior art. The decision of the board is

AFFIRMED.